

EDITORIAL

There can be no issue of greater importance than that of patient safety. Indeed, the foremost interest of the General Medical Council is 'protecting patients'. This issue of *Acupuncture in Medicine* is devoted entirely to aspects of patient safety and consent, and it follows the first multidisciplinary conference on Safety in Acupuncture. The conference took place in June 2001, and involved cooperation between UK organisations representing medical acupuncturists, physiotherapists and traditional practitioners.

The first two papers are the full reports of surveys first published in short form in the *BMJ*. White et al and MacPherson et al surveyed 32,000 and 34,000 consultations respectively. Although MacPherson's team chose not to participate in the first study, they went on to develop the survey methodology with the help of White, and their paper adds new and valuable data to that already provided. This includes some information on positive as well as negative side effects related to acupuncture treatment. The rate of adverse incidents was remarkably congruent between the two studies. The strengths and limitations of both studies are very frankly discussed and may give guidance to future researchers in the field.

Rare and serious traumatic complications are discussed by Peuker and Grönemeyer, who make the point that many of the most severe adverse events are not actually reported by the practitioners responsible – this is obviously somewhat worrying. Using short prospective studies more easily picks up early side effects, but late side effects, such as delays in diagnosis of serious illness, may never be apparent and are picked up by other teams. The recommendation that appropriate knowledge of anatomy needs to be sound and kept up to date with refresher courses is probably pertinent to all practitioners.

Walsh discusses the issues surrounding the potential and actual transmission of infection via acupuncture, and Hoffman considers the pros and cons of skin disinfection. This may be most relevant to the use of semi-permanent needles. Side effects of acupuncture in palliative care are discussed descriptively rather than systematically, as inadequate data exists for this important and vulnerable patient population. The potential for masking disease progression is discussed. Further prospective studies are recommended in all areas of safety, but there are understandable limitations if relying on volunteer practitioners alone. Acupuncture enthusiasts tend to write the most articles about the subject and have the courage to expose adverse effects as well as positive effects. Patient populations may have a different perspective, and further studies are now being planned to gain more information from the latter group.

A consensus document developed by the three largest acupuncture organisations in the UK, stimulated by a letter from Peuker and Grönemeyer, on informed consent before acupuncture treatment is also included in this issue. This is important both legally and in the context of protection of basic human rights. The unique collaboration between these groups with different backgrounds is welcome.

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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

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

<i>Age, mean year (range)</i>	47 (27-71)
<i>Sex</i>	Male 29 (50%) Female 29 (50%)
<i>Occupation</i>	Doctor 36 (61%) Physiotherapist 23 (39%)
<i>Acupuncture training</i>	<24 h: 3 (6%) 25 to 100 h: 20 (37%) > 100 h: 31 (57%)
<i>Duration of practice</i>	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

<i>Event</i>	<i>Cases reported</i>	<i>Mean Incidence per 10,000 consultations (95% CI)</i>	<i>Number (%) of acupuncturists reporting none</i>	<i>Extreme values reported by individual practitioners[†] (rate per 10,000 consultations)</i>
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

<i>Event</i>	<i>Number reported</i>
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 been 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

<i>Event</i>	<i>Recommendation / Comment</i>
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 if it 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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Reference List

1. Healthwatch-Grampian. The use of complementary therapy in the Grampian population. 2000. Grampian Local Health Council.
2. Ernst E. Clinical effectiveness of acupuncture: an overview of systematic reviews. In: Ernst E, White A, editors. *Acupuncture - A Scientific Appraisal*. Oxford: Butterworth Heinemann; 1999. p. 107-27.
3. Ernst E, White A. Life-threatening adverse reactions after acupuncture? A systematic review. *Pain* 1997;71(2):123-6.
4. Rampes H. Adverse reactions to acupuncture. In: Filshie J, White A, editors. *Medical Acupuncture, A Western scientific approach*. Edinburgh: Churchill Livingstone; 1998. p. 375-87.

5. Ernst E, White AR. Acupuncture may be associated with serious adverse events. *BMJ* 2000;320(7233):513-4
6. Ernst E, White AR. Prospective studies of the safety of acupuncture: a systematic review. *Am J Med* 2001;110(6):481-5.
7. Umlauf R. Analysis of the main results of activity of the acupuncture department of Brno hospital. *Acupunct Med* 1988;5(2):16-8.
8. Ernst, G, Strzyz, H, and Hagmeister, H. Incidence of adverse effects during acupuncture therapy. 2000. The Web-Journal of Acupuncture via the Internet, (<http://users.med.auth.gr/~karanik/english/articles/adv.html>), accessed 21 September.
9. 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 Alt Complement Med* 1999;5(3):229-36.
10. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. *Lancet* 2000;356(9237):1255-9.
11. 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.
12. 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.
13. White A, Hayhoe S, Ernst E. Survey of adverse events following acupuncture. *Acupunct Med* 1997;15(2):67-70.
14. Odsberg A, Schill U, Haker E. Acupuncture treatment: side effects and complications reported by Swedish physiotherapists. *Complement Ther Med* 2001;9(1):17-20.
15. BMA Ethics Science and Information Division. *Medical ethics today: its practice and philosophy*. London: BMJ Publishing Group; 1993.
16. 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.
17. Manly BFJ. *Randomization and Monte Carlo methods in biology*. London: Chapman and Hall; 1991.
18. StataCorp. *Stata Statistical Software: Release 6.0*. College Station, TX: Stata Corporation; 1999.
19. Appleton RE. Reflex anoxic seizures. *BMJ* 1993;307(6898):214-5.
20. Melchart, D, Liao, J, and Hager, S. Projektbericht 1994 uber die Erste Deutsche Klinik fur Traditionelle Chinesischen Medizin Kotzting. 1995. Munich, TCM Klinik Kotzting.
21. 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.
22. Yong D, Lim SH, Zhao CX, Cui SL, Zhang L, Lee TL. Acupuncture treatment at Ang Mo Kio community hospital - a report on our initial experience. *Singapore Med J* 1999;40(4):260-4.
23. Thomas KJ, Nicholl JP, Fall M. Access to complementary medicine via general practice. *Br J Gen Pract* 2001;51(462):25-30.
24. Dale J. Practising acupuncture today: A postal questionnaire of medical practitioners. *Acupunct Med* 1996;14(2):104-8.
25. Hayhoe S, Box H. A questionnaire on medical acupuncture practice. *Acupunct Med* 1997;15(2):96-9.
26. Lu GD, Needham J. *Celestial lancets: a history and rationale of acupuncture and moxa*. Cambridge: Cambridge University Press; 1980.
27. Department of Health. An organisation with a memory: report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer. 2000. London, The Stationery Office.
28. Vincent C. The safety of acupuncture. Acupuncture is safe in the hands of competent practitioners. *BMJ* 2001;323(7311):467-8.
29. Hewson B. Why the human rights act matters to doctors. *BMJ* 2000;321(7264):780-1.

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.¹⁻³ 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.⁴ With the recent House of Lords Report emphasising the public policy issues where there are risks associated with complementary medicine,³ it is timely to report here on this

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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,^{5,6} 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,^{7,8} 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,⁹ 28,000 in Taiwan,¹⁰ and 65,000 in Japan.¹¹

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.^{12,13} 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.¹² 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,¹² 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.³

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 al⁷ in using Hanley's Rule of Threes.¹⁴ 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,¹² 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

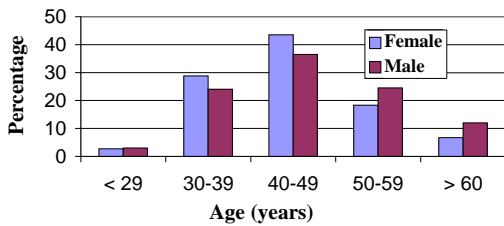
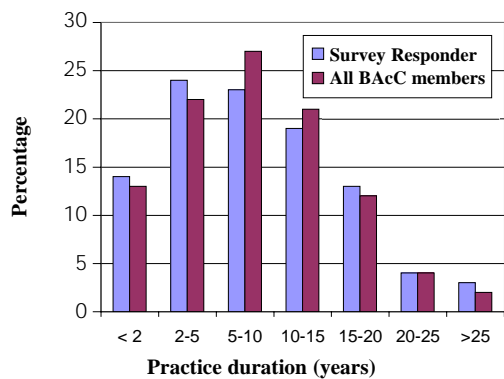


Table 2 Relationship of survey responders to BAAC membership in regards to practice duration



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.¹⁵ 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.¹⁵ 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

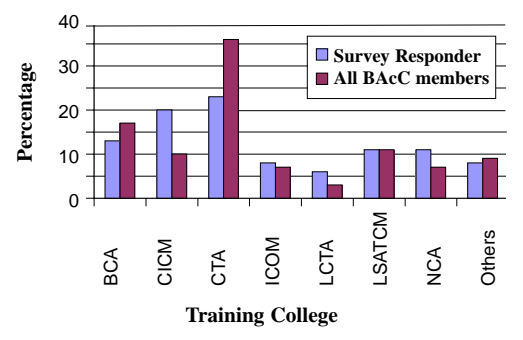
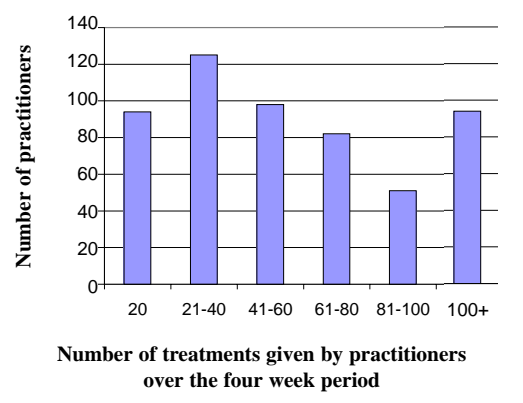


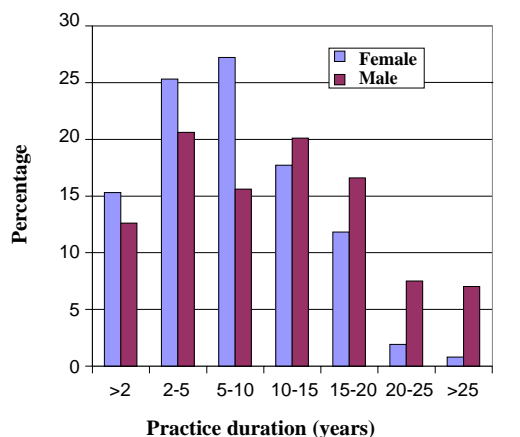
Table 5 Cluster bar chart of practitioners by number of treatments over the 4 week period



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.^{16;17} 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	
Total	43	

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
Systemic Mild Transient Reactions to Treatment				
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
Aggravations of Existing Symptoms				
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
Local Mild Transient Reactions to Treatment				
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
Other Mild Transient Reactions to Treatment				
	288	0.8	0.7	0.9

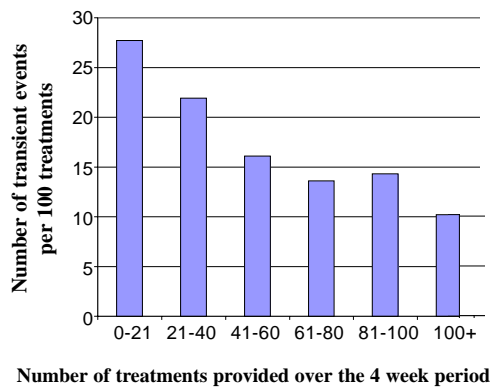
drowsiness in 368 (1.1%), dizziness in 211 (0.6%), nausea in 78 (0.3%) and feeling faint (but not actually fainting) in 73 (0.2%). The second category of mild transient reactions, aggravations of existing symptoms, were reported to have occurred in 966 (2.8%) treatments, and following 830 (2.4%) of these 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,¹² all previous large scale prospective surveys have been based within hospital or acupuncture teaching clinics.⁹⁻¹¹ 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,¹⁴ 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.¹² 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,¹¹ 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.¹⁸ 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.¹⁷ Estimates of non-steroidal drug related deaths range from 2000 to 2,500 a year in the UK.^{18;19} 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'.²⁰ 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,¹¹ 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 al¹² 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,¹² 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.¹¹ 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.⁸ In Japan this effect is called the 'Menken phenomenon', which Yamashita et al describe as a 'healing crisis'.¹¹ 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.¹² 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%.¹² 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%.¹² 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?²⁰ 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,²¹ 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.²⁶ 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 BAcC. 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 BAcC 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.

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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.

Rare But Serious Complications of Acupuncture: Traumatic Lesions

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Summary

Acupuncture has a reputation among the public of being safe. Although recently performed prospective studies on the frequency of adverse effects of acupuncture found no severe complication, since 1965 many case reports of serious or even life-threatening incidents caused by acupuncture have appeared in the scientific literature.

The most frequently reported complications are pneumothorax and lesions of the spinal cord. Severe injuries of peripheral nerves and blood vessels due to acupuncture seem to be very rare.

Although case reports do not produce reliable data on the frequency of adverse events, information on sources of application errors can be extracted to increase the quality of acupuncture in education and therapy.

All traumatic injuries described in this article could be avoided if practitioners had better anatomical knowledge, applied existing anatomical knowledge better, or both.

Keywords

Adverse effects, risk, traumatic complications, anatomy.

Introduction

Acupuncture has a reputation among the public of being safe. Recently, some prospective studies on the frequency of adverse effects from acupuncture have been performed and were published in the *BMJ*.^{1,2} In more than 60,000 interventions performed by skilled acupuncturists no serious complications were found. Since 1965, however, publications have repeatedly reported serious and

even life-threatening incidents in association with acupuncture treatment. Several authors have collated lists of complications caused by or associated with acupuncture.^{3,4} In general, the reported adverse effects of acupuncture therapy can be categorized in the following groups:

delayed or missed diagnosis (ie, orthodox diagnostic categories);

deterioration of disorder under treatment;

vegetative reactions (eg, syncope, vertigo, sweating);

bacterial and viral infection (e.g. hepatitis B, C and human immunodeficiency virus infection);

trauma of tissues and organs.

Depth of insertion of the acupuncture needles varies from a few millimeters to several centimeters. The tip of the needle often lies in a muscle, or overlies other structures, including the nerves and pleura; therefore, acupuncturists need a working knowledge of anatomy to avoid causing direct trauma.⁵

Traumatic lesions can be divided according to the following topographical and structural characteristics:

thoracic viscera;

abdominal or retroperitoneal viscera;

peripheral nerves;

central nervous system;

blood vessels.

The aim of this article is to review the reports of traumatic injuries associated with acupuncture and discuss how these adverse effects may be reduced by increased awareness of normal anatomy and anatomical variations.

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*Thoracic viscera**Cardiac Tamponade*

To our knowledge, six cases of injuries to the heart and the pericardium have been described in the scientific literature so far;⁶⁻¹¹ we were notified of two more cases during the last year by colleagues from France and Canada. Two of the reported cases ended fatally. Another case-report, which is often cited in reviews of fatalities in acupuncture, describes the self-insertion of a sewing-needle in the heart, which clearly has nothing to do with acupuncture.¹² One of the fatal cases was caused by lack of awareness of the sternal foramen.

The sternal foramen is a congenital abnormality due to an incomplete fusion of the sternal plates. It exists in approximately 5% to 8% of the population, and is usually located at the level of the fourth intercostal space (ie, precisely at the acupuncture point conception vessel 17 (CV17)). It cannot be identified by standard chest x-ray films. Using computed tomography (CT), Stark found this variation in 4.8% of their sample.¹³ Cooper et al detected a sternal foramen in 6.7% of all autopsies they performed.¹⁴ Schratter et al evaluated 100 chest CT scans with reference to the incidence of the sternal foramen and its features.¹⁵ They distinguished four types of this anomaly, varying from incomplete retraction of the sternal cortex to complete foraminal defects. A sternal foramen was present in 8%, and was of sufficient size in 6% to constitute a risk of complications during medical interventions. The distance between the surface of the skin and the posterior surface of the sternum was estimated to be only about 13 to 19 mm. In our own studies on cadavers of adult people we found distances with a range between 15 and 25 mm.⁵ Palpation prior to using acupuncture cannot reliably detect the abnormality because tendon fibres, thin connective tissue, or bone lamella may conceal the foramen. It is clearly impractical for all patients to undergo CT or magnetic resonance imaging before acupuncture; therefore, acupuncturists must be aware of this frequent variation when treating patients with asthma or chest pain. Points over the sternum have to be needled tangentially and superficially to prevent serious incidents.

Pneumothorax

The most frequently reported injury caused by acupuncture needles is pneumothorax. Some authors consider this complication to be regularly seen by emergency physicians.¹⁶ Pneumothorax chiefly occurs when the needles are placed in a parasternal or supraclavicular site; the latter without taking notice that the borders of the pleura and lung are situated well above the clavicles. Acupuncture to the paravertebral, infraclavicular, and lateral thoracic regions may also cause pneumothorax. Descriptions of more than 90 such incidents can be found in scientific publications;¹⁷⁻⁵⁴ in two cases, the incidents resulted in death.^{17,18} In a comprehensive epidemiological survey in Japan, out of 255 cases of secondary pneumothorax, 9% turned out to be caused by acupuncture.⁵⁵ In a census carried out in Norway in 1995, 33 of 1332 Norwegian acupuncturists admitted that pneumothorax had occurred during treatment.⁵⁶ In a systematic review of the Japanese literature, Yamashita et al found 25 cases of pneumothorax in 89 articles which reported 124 incidents of acupuncture.⁵⁷ In 2001, Odsberg and colleagues published a prospective study on adverse effects of acupuncture.⁵⁸ In more than 9000 treatments the Swedish group found no major complication. Between completion of the survey and the publication date, three cases of pneumothorax due to acupuncture were reported to the National Board of Health and Welfare in Sweden.

Pneumothorax is a potentially serious adverse effect; avoiding it requires a clear understanding of the actual position and borders of the pleurae and lungs and the thickness of the soft tissue covering them. The most dangerous points, according to the literature, are as follows: in the supraclavicular region, treatment to ST11 and 12 has caused injuries of the lung; in the infraclavicular region, LU2, ST13, and KI27 are potentially risky. Furthermore, the parasternal points on the kidney meridian (KI22 to 27) and the points of the stomach meridian in the midclavicular line (ST12 to 18) require particular care when needling.

From postmortem examinations, we have found that a puncture depth of 10 to 20 mm, either parasternally or in the region of the midclavicular line, can reach the lungs.⁵ It should also be noted that, depending on the thickness of the needle and the amount of tissue resistance, a variable degree of compression of the soft tissue takes place, so that the actual puncturing depth may be considerably greater than the length of the needle. In the region of the lateral line of the bladder meridian, located approximately on the medial scapular line (BL41 to 54), the surface of the lung is about 15 to 20 mm beneath the skin.

Abdominal viscera

In principal the needling of points on the stomach, spleen, kidney and conception vessel meridians on the front of the body, and the bladder meridian on the back, can lead to injuries of abdominal or retroperitoneal organs. Lesions of abdominal viscera, however, are rarely reported. One paper reported the finding of a foreign body in the left kidney that turned out to be part of an acupuncture needle.⁵⁹ Occasional reports deal with lesions of the urinary bladder and the intestine.⁶⁰⁻⁶⁵ A poll of participants of our acupuncture courses showed that the respective points are needled rather seldom. Perhaps therapists assume the abdominal regions as particularly vulnerable. We found that the thickness of the soft tissue in the regions of the kidney and the stomach meridian, in adults with normal weight, was between 2 and 4 cm.⁵ Provided that a proper needling technique is performed there should be minimal risk of reaching the abdominal cavity.

Peripheral nerves

Injuries of peripheral nerves are reported infrequently. We found two published case reports clearly related to acupuncture. In one case, a broken needle in the carpal tunnel caused a neuropathy of the median nerve.⁶⁶ It has to be noted that the median nerve may be damaged by needling the points PC6 or 7. In the other case, a needle inserted in the region of the fibular head led to a peroneal nerve palsy resulting in drop foot.⁶⁷ The

common peroneal nerve is particularly variable in its course. In 10 to 20% it takes a rather high course and intersects the acupuncture point GB34. The bladder meridian points BL39 and 40 have a close topographical relationship to the common peroneal and the tibial nerve, which may be reached in 2 to 3 cm depth. Standard textbooks of acupuncture recommend a needling depth of 0.5 to 1 Cun (approximately 1 to 2.5 cm in most adults).

In view of the vulnerability of many peripheral nerves and their proximity to acupuncture points, it is surprising that transient or persistent nerve injuries are not reported more frequently. On the other hand the needling of epineural structures is likely to be an important principle in the effectiveness of several acupuncture points, e.g. BL54 (sciatic nerve) or KI3 (posterior tibial nerve).

Central nervous system

We found 10 cases of injuries to the spinal cord or spinal nerve roots in the scientific literature.⁶⁸⁻⁸¹ In four of the cases migration of needle fragments was responsible for the lesion, and six cases were caused by direct injury. The level of the lesion varied from segment C1 through C2 to segment S1 (segment C1 to C2, four cases; segment C6, one case; segment L4 to L5, two cases; and segment S1, one case). Focal neurological signs as well as general complications up to paraplegia have been reported. Moreover, there have been several cases of arachnoiditis or subarachnoid haemorrhage. The distance from the surface of the skin to the spinal cord or the roots of the spinal nerves ranges from 25 to 45 mm, depending on the constitution of the patient. Deep needling of points of the inner line of the bladder meridian (BL11 to 20) was particularly likely to cause lesions of the spinal cord or the spinal nerve roots.

In Germany many acupuncturists are timid in needling points on the neck, especially GB20 and BL10. Most textbooks of acupuncture remind their readers to needle these points carefully because of the assumed proximity to the vertebral artery and the medulla oblongata. Our own investigation on cadavers of normally built adult people indicated difficulties in reaching these

structures with normal acupuncture needles. They lie at a depth of about 4 to 6 cm. We found no case-reports that described a lesion of the vertebral artery, however, there has been a report that suggests direct needling of the medulla from the point GV16 resulting in a haemorrhage into the fourth ventricle.⁸² This point has been used in western medicine for cisternal puncture.

Blood vessels

There are four reports so far concerning lesions of blood vessels associated with acupuncture. A case of pseudoaneurysm of the costocervical artery probably caused by acupuncture was reported in 1994.⁸³ A woman had been treated for shoulder stiffness several times with 20 to 30 needles around the spines of the scapulae at each session. After the fourth session she noticed a nodule at her left shoulder and experienced a sharp pain. After diagnosis with CT and angiography, surgery was performed and a partially thrombosed pseudoaneurysm in the region of the costocervical artery was found. There was another case report of an aneurysm caused by acupuncture in 1996. Deep puncturing of BL40 caused a lesion of the posterior wall of the popliteal artery that led to a false aneurysm.⁸⁴ A deep vein thrombophlebitis after acupuncture in the region of the upper calf, with leg pain 48 hours after the treatment, has also been reported.⁸⁵ The anatomical and temporal connection strongly supports a relationship between needle insertion and phlebitis. Another patient, who had been receiving anticoagulant therapy, developed an anterior compartment syndrome in the lower leg after acupuncture.⁸⁶ Needling was performed about 5cm below the lateral aspect of the knee - probably at the point GB34 or ST36.

As is the case with peripheral nerves, it seems likely that lesions of peripheral blood vessels caused by acupuncture may frequently be undetected or unreported. We understand that stimulation of the perivascular networks of autonomic nerves at some points may be important to achieve a therapeutic effect, e.g. LU9 (radial artery) or HT7 (ulnar artery).

Comment

The use of acupuncture is becoming increasingly popular among medical as well as non-medical therapists. Causation of adverse effects is sometimes difficult to determine beyond doubt. Case reports do not produce reliable data on the frequency of adverse events. There are several reasons for suspecting underreporting. Few people admit their own mistakes and even fewer tend to publish them. The cases that do appear are generally reported by those professions that handle the complications (for example emergency physicians in the case of pneumothorax). Unfortunately, these specialists often lack specific knowledge of acupuncture points and theory, so their reports may not always include the specific needling details that are important to acupuncturists. Furthermore, the papers usually appear in the journals of the specialists who manage the complications, rather than in acupuncture journals. The scientific journals themselves generally only publish reports on rare events, and it appears that some countries – perhaps for political reasons – do not publish reports of adverse events at all.

It is important to recognize that even one avoidable adverse event is one too many. All of the traumatic injuries described in this article could have been avoided if practitioners had had better anatomical knowledge, applied existing anatomical knowledge better, or both. It should be emphasized that medical practitioners are not exempt from the need to study anatomy relevant to acupuncture, since they are unlikely to have needed this information in conventional medical practice. Courses offering education targeted toward precise objectives in anatomical knowledge are scarce. All training and regulatory organisations of acupuncture, including statutory governmental organisations, have a duty to consider the content and effectiveness of training in anatomy as a priority. Rigorous training curricula with tests of knowledge and refreshment throughout a lifetime of practice are needed. The data presented in this review may provide a basis for deciding what needs to be included in such a

curriculum, although not all potentially dangerous points have necessarily been described.

Reference list

1. 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.
2. 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.
3. Ernst E, White A. Life-threatening adverse effects of acupuncture? A systematic review. *Pain* 1997;71(2):123-126.
4. Rampes H, Peuker ET. Safety of acupuncture In: Ernst E, White AR editors. *Acupuncture - a scientific appraisal*. London: Butterworth-Heinemann; 1999. p. 128-52.
5. Peuker ET, White AR, Ernst E, Pera F, Filler TJ. Traumatic Complications of Acupuncture, Therapists Need to Know Human Anatomy. *Arch Fam Med* 1999;8:553-8.
6. Nieda S, Abe T, Kuribayashi R, Sato M, Abe S. [Case of a cardiac injury resulting from acupuncture]. *Kyobu Geka* 1973;26(12):881-3.
7. Hasegawa J, Noguchi N, Yamasaki J et al. Delayed cardiac tamponade and hemothorax induced by an acupuncture needle. *Cardiology* 1991;78(1):58-63.
8. Cheng TO. Pericardial effusion from self-inserted needle in the heart. *Eur Heart J* 1991;12(8):958.
9. Halvorsen TB, Anda SS, Naess AB, Levang OW. Fatal cardiac tamponade after acupuncture through congenital sternal foramen. *Lancet* 1995;345(8958):1175.
10. Kataoka H. Cardiac tamponade caused by penetration of an acupuncture needle into the right ventricle. *J Thorac Cardiovasc Surg* 1997;114(4):674-6.
11. Kirchgatterer A, Schwarz CD, Holler E, Punzengruber C, Hartl P, Eber B. Cardiac tamponade following acupuncture. *Chest* 2000;117(5):1510-1.
12. Schiff AF. A fatality due to acupuncture. *Med Times (Lond)* 1965;93:630-1.
13. Stark P. Midline sternal foramen: CT demonstration. *J Comput Assist Tomogr* 1985;9(3):489-90.
14. Cooper PD, Stewart JH, McCormick WF. Development and morphology of the sternal foramen. *Am J Forensic Med Pathol* 1988;9(4):342-7.
15. Schratte M, Bijak M, Nissel H, Gruber I, Schratte-Sehn AU. [The foramen sternale: a minor anomaly—great relevance]. *Rofo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahr* 1997;166(1):69-71.
16. Kelsey JH. Pneumothorax following acupuncture is a generally recognized complication seen by many emergency physicians. *J Emerg Med* 1998;16(2):224-5.
17. Gee D. Fatal pneumothorax due to acupuncture. *BMJ* 1984;288(6411):114.
18. Brettel HF. [Acupuncture as a cause of death]. *MMW Muench Med Wochenschr* 1981;123(3):97-8.
19. Lewis-Driver DJ. Pneumothorax associated with acupuncture. *Med J Aust* 1973;2(6):296-7.
20. Goldberg I. Pneumothorax associated with acupuncture. *Med J Aust.* 1973;1(19):941-2.
21. Waldman I. Pneumothorax from acupuncture. *N Engl J Med* 1974;290(11):633.
22. Corbett M, Sinclair M. Acu- and pleuro-puncture. *N Engl J Med* 1974;290(3):167-8.
23. Ritter HG, Tarala R. Pneumothorax after acupuncture. *BMJ* 1978;2(6137):602-3.
24. Bodner G, Topilsky M, Greif J. Pneumothorax as a complication of acupuncture in the treatment of bronchial asthma. *Ann Allergy* 1983;51(3):401-3.
25. Stack BH. Pneumothorax associated with acupuncture. *BMJ* 1975;1(5949):96.
26. Fraser RM. An unusual complication of acupuncture. *Can Med Assoc J* 1974;3:388-93.
27. Schnorrenberger C. Akupunktur: Schmerzschwelle wird erhöht. *Selecta* 1978;3:165.
28. Valenta LJ, Hengesh JW. Pneumothorax caused by acupuncture. *Lancet* 1980;2(8189):322.
29. Wex P, Weig J. [Aetiology and treatment of spontaneous pneumothorax]. *Prax Klin Pneumol* 1978;32(9):593-7.
30. Carron H, Epstein BS, Grand B. Complications of acupuncture. *JAMA* 1974;228(12):1552-4.
31. Willms D. Possible complications of acupuncture. *West J Med* 1991;154(6):736-7.
32. Kropp R, Hassler R. [Accidental pneumothorax following injections and acupuncture in the thoracic region]. *Med Welt* 1983;34(41):1143-4.
33. Mazal DA, King T, Harvey J, Cohen J. Bilateral pneumothorax after acupuncture. *N Engl J Med* 1980;302(24):1365-6.
34. Wright RS, Kupperman JL, Liebhaber ML (1991) Bilateral tension pneumothoraces after acupuncture. *West J Med* 154(1):102-3.
35. Schlenker G, Huegel A. [Complications of acupuncture]. *Dtsch Med Wochenschr* 1976;101(7):241-3.
36. Kuiper JJ. Pneumothorax as complication of acupuncture. *JAMA* 1974;229(11):1422.
37. Vilke GM, Wulfert EA. Case reports of two patients with pneumothorax following acupuncture. *J Emerg Med* 1997;15(2):155-7.
38. Marchuk IK. [Pneumothorax developing as a result of acupuncture in the treatment of bronchial asthma]. *Vrach Delo* 1989;(5):101-2.
39. Gray R, Maharajh GS, Hyland R. Pneumothorax resulting from acupuncture. *Can Assoc Radiol J* 1991;42(2):139-40.
40. Guerin JM, Tibourtine O, Lhote F, Segrestaa JM. [2 cases of pneumothorax following acupuncture]. *Rev Med Interne* 1987;8(1):71.
41. Huet R, Renard E, Blotman MJ, Jaffiol C. Unrecognized post-acupuncture pneumothorax in a female patient with anorexia nervosa. *Presse Med* 1990;19(30):1415.
42. Henneghien C, Bruart J, Remacle P. [A new iatrogenic pathology: pneumothorax after acupuncture]. *Rev Pneumol Clin* 1984;40(3):197-9.
43. Morrone N, Freire JA, Ferreira AK, Dourado AM. [Iatrogenic pneumothorax caused by acupuncture]. *Rev Paul Med* 1990;108(4):189-91.
44. Schneider LB, Salzberg MR. Bilateral pneumothorax following acupuncture. *Ann Emerg Med* 1984;13:643.
45. Carette MF, Mayaud C, Houacine S, Milleron B, Toty L, Akoun G. [Treatment of an asthmatic crisis by

- acupuncture. Probable role in the onset of pneumothorax with development to status asthmaticus]. *Rev Pneumol Clin* 1984;40(1):69-70.
46. Smith PF, Rauscher CR. Complication of acupuncture. *JAMA* 1974;229:1286.
 47. Takishima, T. Pneumothorax as a complication of acupuncture in the treatment of bronchial asthma. *Ann Allergy* 1983;51:402-3.
 48. Candela-Blanes A, Hernandez-Blasco L, Martin-Serrano C, Romero-Candeira S. Pneumothorax as a complication of acupuncture. *An Med Interna* 1995;12:412-3.
 49. Despars JA, Sassoon CS, Light RW. Significance of iatrogenic pneumothoraces. *Chest* 1994;105(4):1147-50.
 50. Devouassoux G, Kelkel E, Delormas P. Bilateral pneumothorax with an unusual origin. *Rev Pneumol Clin* 1994;50(4):186-7.
 51. Marchuk IK, Kuz'mich VN, Marchuk LI, Ordynskii NL. [Iatrogenic pneumothorax]. *Lik.Sprava* 1993;(10-12):81-2.
 52. Olusanya O, Mansuri I. Pneumothorax following acupuncture. *J Am Board Fam Pract* 1997;10(4):296-7.
 53. Jones KS. Chest pain and breathlessness after acupuncture—again. *Med J Aust* 1998;169(6):344.
 54. Jawahar D, Elapavaluru S, Leo PJ. Pneumothorax secondary to acupuncture. *Am J Emerg Med* 1999;17:310.
 55. Nakamura H, Konishiike J, Sugamura A, Takeno Y. Epidemiology of spontaneous pneumothorax in women. *Chest* 1986;89(3):378-82.
 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.
 57. Yamashita H, Tsukayama H, White AR, Tanno Y, Sugishita C, Ernst E. Systematic review of adverse events following acupuncture: the Japanese literature. *Complement Ther Med* 2001;9(2):98-104.
 58. Odsberg A, Schill U, Haker E. Acupuncture treatment: side effects and complications reported by Swedish physiotherapists. *Complement Ther Med* 2001;9(1):17-20.
 59. Yuzawa M, Hara Y, Kobayashi Y, Ishiyama S, Tozuka K, Nakamura S *et al.* [Foreign body stone of the ureter as a complication of acupuncture: report of a case]. *Hinyokika Kyo* 1991;37(10):1323-7.
 60. Keller WJ, Parker SG, Garvin JP. Possible renal complications of acupuncture. *JAMA* 1972;222(12):1559.
 61. Kho Hing Gwan (1975) cited in van Duk, P.: Complicaties bij acupunctuur. *Ned T Geneesk* 1980;124:1404-8.
 62. Peacher (1975) cited in van Duk, P.: Complicaties bij acupunctuur. *Ned T Geneesk* 1980;124:1404-8.
 63. Wiese (1977) cited in van Duk, P.: Complicaties bij acupunctuur. *Ned T Geneesk* 1980;124:1404-8.
 64. Worsley (1973) cited in van Duk, P.: Complicaties bij acupunctuur. *Ned T Geneesk* 1980;124:1404-8.
 65. Matsuyama H, Nagao K, Yamakawa GI, Akahoshi K, Naito K. Retroperitoneal hematoma due to rupture of a pseudoaneurysm caused by acupuncture therapy. *J Urol* 1998;159(6):2087-8.
 66. Southworth SR, Hartwig RH. Foreign body in the median nerve: a complication of acupuncture. *J Hand Surg [Br.]* 1990;15(1):111-2.
 67. Sobel E, Huang EY, Wieting CB. Drop foot as a complication of acupuncture injury and intragluteal injection. *J Am Podiatr Med Assoc* 1997;87(2):52-9.
 68. Isu T, Iwasaki Y, Sasaki H, Abe H. Spinal cord and root injuries due to glass fragments and acupuncture needles. *Surg Neurol* 1985;23(3):255-60.
 69. Noumi T, Yamauchi Y, Kamimura K *et al.* A broken acupuncture needle migrated into the spinal canal. *Nippon Iji Shinpo* 1976;4:799-803.
 70. Sato M, Yamane K, Ezima M, Sugishita Y, Nozaki H. [A case of transverse myelopathy caused by acupuncture]. *Rinsho Shinkeigaku* 1991;31(7):717-9.
 71. Kishikawa K, Nakae Y, Fujiwara S, Namiki A, Mori T. A spinal cord injury caused by acupuncture needles. *Pain Clinic* 1990;3(3):179-84.
 72. Matsui S, Matsuoka K, Nakagawa K, Kohno K, Sakaki S. [Cervical spinal cord injury caused by a broken acupuncture needle: a case report]. *No Shinkei Geka* 1992;20(4):499-503.
 73. Kida Y, Naritomi H, Sawada T, Kuriyama Y, Ogawa M, Miyamoto S. Cervical spinal cord injury caused by acupuncture. *Arch Neurol* 1988;45(8):831.
 74. Hasegawa O, Shibuya K, Suzuki Y, Nagatomo H. [Acupuncture needles, straying in the central nervous system and presenting neurological signs and symptoms]. *Rinsho Shinkeigaku* 1990;30(10):1109-13.
 75. Sasaki H, Abe H, Iwasaki Y, Tsuru M, Itoh T. [Direct spinal cord and root injury caused by acupuncture—report of 2 cases]. *No Shinkei Geka* 1984;12(10):1219-23.
 76. Kondo A, Koyama T, Ishikawa J, Yamasaki T. Injury to the spinal cord produced by acupuncture needle. *Surg Neurol* 1979;11(2):155-6.
 77. Shiraishi S, Goto I, Kuroiwa Y, Nishio S, Kinoshita K. Spinal cord injury as a complication of an acupuncture. *Neurology* 1979;29(8):1188-90.
 78. Maruoka N, Kinoshita K, Wakisaka S. [Spinal cord injury by a broken acupuncture needle—a case report]. *No Shinkei Geka* 1986;14(6):785-7.
 79. Tomonaga I, Miyazaki M, Kondo T, Kono M, Ueno T. Migration of the acupuncture needles into the cervical spinal cord. *Ortho Traumatol (Fukuoka)* 1984;32:123-5.
 80. Kojima Y, Ono K, Ogino H, Okada K, Kimura T. Migration of the needle of acupuncture into the cervical spinal canal. Report of four cases. *Chuba Nippon Seikeigeka Gakkai Zasshi* 1985;23:292-4.
 81. Drake TE. Complication of acupuncture. *JAMA* 1974;229(10):1285-6.
 82. Choo DC, Yue G. Acute intracranial hemorrhage caused by acupuncture. *Headache* 2000;40(5):397-8.
 83. Fujiwara T, Tanohata K, Nagase M. Pseudoaneurysm caused by acupuncture: a rare complication. *AJR Am J Roentgenol* 1994;162(3):731.
 84. Lord RV, Schwartz P. False aneurysm of the popliteal artery complicating acupuncture. *Aust NZ J Surg* 1996;66(9):645-7.
 85. Blanchard BM. Deep vein thrombophlebitis after acupuncture. *Ann Intern Med* 1991;115(9):748.
 86. Smith DL, Walczyk MH, Campbell S. Acupuncture needle induced compartment syndrome. *West J Med* 1986;144(4):478-9.

Control of Infection in Acupuncture

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Summary

This paper is an update on infections, and potential infections, related to acupuncture, and a brief review of the relevant infection control procedures.

There is no evidence at present to suggest that significant numbers of infections are being transmitted through standard acupuncture treatments in the UK. None the less, good infection control is essential. Like any other science, new research forces infection control to evolve and refine its procedures. Acupuncturists need to constantly review their standards as new viruses and risks are identified.

Keywords

Acupuncture, infection control, hepatitis B virus.

Introduction

Acupuncture has been shown to be a safe procedure provided it is performed by skilled and competent practitioners. Two recent reviews have shown that the risk of problems is extremely low.^{1,2} No infection related complications were reported in these reviews.³ Improvements in sterilisation have led to fewer outbreaks of blood borne viruses since the 1980s. Control of infection procedures have continued to be developed and improved in recent years. Cases of serious bacterial infections, such as staphylococcal septicaemia and subacute bacterial endocarditis, have been reported in association with acupuncture treatment, but they are rare.^{4,7}

This paper is an update on infections, and potential infections, related to acupuncture, and a brief review of the relevant infection control procedures.

Specific Infections

Hepatitis B

Rampes & James reported a total of 126 cases of hepatitis B related to acupuncture in a review published in 1995.⁸ Outbreaks of hepatitis B virus (HBV) were recorded in 1997, when 36 cases were diagnosed following acupuncture using hollow needles and inadequate sterilisation.⁹ Two outbreaks in Germany, in 1978 (three cases),¹⁰ and 1976-83 (20 cases),¹¹ were the result of inadequate sterilisation. Sixteen patients in Israel contracted HBV as a result of inadequate sterilisation.¹² In a Rhode Island outbreak 35 patients were HBV positive, following treatment from an acupuncturist who was hepatitis B IgM positive.¹³ In a Florida cluster six cases of HBV were associated with acupuncture performed in a chiropractic clinic. The clinic reused acupuncture needles after immersing them overnight in a 1:750 solution of benzalkonium chloride.¹⁴

Five cases of hepatitis B were confirmed in patients attending an acupuncture clinic in South London in 1990-92. The strain of HBV found in two of the patients and the acupuncturist were indistinguishable, suggesting that the acupuncturist may have been the source of infection in these two cases. Person to person spread may have occurred in the remaining cases due to poor control of infection procedures.¹⁵

Between 1985 and 1997 in England and Wales there were five notified cases of acute hepatitis B associated with acupuncture (Ramsey M, personal communication). In 1998 a medical practitioner in North London was responsible for transmitting HBV to 36 patients using auto-haemotherapy (re-injection of own blood) at acupuncture sites.¹⁶

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Whilst sterile, disposable needles were used for each patient, the same saline bottle was reused, with contaminated needles, to draw fluid for dilution of blood before reinjection.

There are approximately 800 cases of acute hepatitis B infection diagnosed in the UK per annum. This number has fallen since the late 1980s, when there were approximately 1200 cases. In addition to diagnosed acute cases there are an estimated 400 asymptomatic cases of hepatitis B. Approximately 10% of cases become carriers. A small percentage of cases carry the e antigen, and this makes the individuals concerned high risk carriers. It is estimated that there are four million infectious doses of HBV in a drop of blood (Hoffman P, personal communication). Nausea, vomiting, loss of appetite, weight loss and flu like illness are the major presenting symptoms in cases of acute hepatitis B, and jaundice and pruritus are typical presenting signs.

Other Blood Borne Viruses

There have been no cases in the UK of human immunodeficiency virus (HIV) where a causal link with acupuncture has been established. There have been no reported cases of hepatitis C associated with acupuncture, apart from a single case in the auto-haemotherapy outbreak detailed above. Hepatitis C rarely presents with acute jaundice. Most of the estimated 300,000 cases in the UK are asymptomatic.¹⁷ The majority have been associated with drug misuse, via infected needles, in the 1970s and 80s. Eighty percent of HIV infected patients develop chronic hepatitis, often presenting with chronic fatigue syndrome. Some of these may appear in acupuncture clinics, seeking treatment.

Variant Creutzfeldt-Jacob Disease

There is no evidence to link any of the current 100 cases of variant CJD in the UK with acupuncture. Variant CJD due to abnormal prion protein is thought to be associated with consumption of infected UK beef during the 1980s, before meat hygiene regulations were introduced and enforced. Initial symptoms are psychiatric, with depression

and anxiety; later symptoms include unsteadiness and hallucinations. In the majority of cases death occurs within 2 years.¹⁸

Control of Infection Measures

Only single use, disposable acupuncture needles should now be used on patients. The extra cost of needles should be easily offset by the removal of the need to purchase, upgrade and maintain bench top steam sterilisers, and of the time spent sterilising needles. Single use, disposable needles remove the risks of Hepatitis B and C and HIV, not only for patients, but also for the acupuncturist who may contract the infection through needle stick injuries whilst handling needles.

A further reason for single use, disposable needles is to remove the remote risk of vCJD. Sterilisation using an autoclave does not remove the prion protein that causes vCJD. Although no cases of vCJD have been associated with acupuncture, it is prudent for the industry to eliminate this remote risk by using single use, disposable needles.

Used needles should be discarded immediately after use in suitable disposal containers complying with British Standard specifications. Guidance on the law relating to the safe disposal of, and responsibility for, clinical waste may be found in the BMA code of practice.¹⁹

Disposable plastic introducers reduce the risk of the acupuncture needle grazing the operator's fingers and therefore may be advantageous in certain circumstances. These introducers should be disposed of between patients.

Occupational Health

Hepatitis B immunisation is advisable for acupuncturists, as they are in contact with blood and body fluids through the use of needles. A course of three injections (at 0, 1, and 6 months) is very effective in protecting against HBV.²⁰ HBV antibody levels should be measured after the course to ensure seroconversion has occurred. The vaccine is very safe, with minimal side effects; however, redness at the injection site is common. Current advice recommends a booster after 5 years

where there is an ongoing risk of hepatitis. This advice is under review and is expected to change in the near future.

Needlestick Injuries

These can be reduced by ensuring that the storage container is replaced once it is 2/3 full. Latex gloves reduce the risk of infection to the operator, and, if used, should be changed between patients. Needles can penetrate gloves, but the volume of blood entering the skin is reduced by the shearing effect of the glove on the needle.

All needlestick injuries should be dealt with in Accident and Emergency departments. As hepatitis B has an incubation period of between two and six months, un-immunised people can receive post-exposure prophylactic hepatitis B immunisation. In addition, risk assessment for HCV and HIV can be carried out. Counselling is available for Hepatitis C and HIV. Anti-retroviral drugs for HIV may be given in rare circumstances where risk assessment indicates that significant exposure to HIV has occurred.

Universal Precautions

Regular handwashing is good practice and one of the main ways of reducing transmission of infections (bacterial, viral and fungal) between patients. Wounds and skin lesions should be covered with waterproof dressings. Protective clothing reduces the spread of infection. Blood spillages should be cleaned promptly, wearing gloves and using household bleach and paper towels. Contaminated items should be discarded in a clinical waste bag.

Conclusion

There is no evidence at present to suggest that significant numbers of infections are being transmitted through standard acupuncture treatments in the UK. None the less, good infection control is essential. Like any other science, new research forces infection control to evolve and refine its procedures. Acupuncturists need to constantly review their standards as new viruses and risks are identified.

Reference list

1. 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.
2. 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.
3. Vincent C. The safety of acupuncture. Acupuncture is safe in the hands of competent practitioners. *BMJ* 2001;323(7311):467-8.
4. Pierik MG. Fatal Staphylococcal septicemia following acupuncture: report of two cases. Occurrence of Staphylococcal septicemia following acupuncture emphasizes need for thorough medical evaluation before such procedures. *R I Med J* 1982;65(6):251-3.
5. Izatt E, Fairman M. Staphylococcal septicaemia with disseminated intravascular coagulation associated with acupuncture. *Postgrad Med J* 1977;53(619):285-6.
6. Jefferys DB, Smith S, Brennand-Roper DA, Curry PV. Acupuncture needles as a cause of bacterial endocarditis. *BMJ* 1983;287(6388):326-7.
7. Lee RJ, McIlwain JC. Subacute bacterial endocarditis following ear acupuncture. *Int J Cardiol* 1985;7(1):62-3.
8. Rampes H, James R. Complications of acupuncture. *Acupuncture Med* 1995;13(1):26-33.
9. Boxall EH. Acupuncture hepatitis in the West Midlands, 1977. *J Med Virol* 1978;2(4):377-9.
10. Kobler E, Schmuziger P, Hartmann G. [Hepatitis following acupuncture]. *Schweiz Med Wochenschr*. 1979;109(46):1828-9.
11. Schmid E, Hortling G, Kammuller H. [Inoculation hepatitis caused by acupuncture. Clinical cases studied over a 9-year period]. *Fortschr Med* 1984;102(35):862-5.
12. Slater PE, Ben Ishai P, Leventhal A, Zahger D, Bashary A, Moses A *et al*. An acupuncture-associated outbreak of hepatitis B in Jerusalem. *Eur J Epidemiol* 1988;4(3):322-5.
13. Kent GP, Brondum J, Keenlyside RA, LaFazia LM, Scott HD. A large outbreak of acupuncture-associated hepatitis B. *Am J Epidemiol* 1988;127(3):591-8.
14. Stryker WS, Gunn RA, Francis DP. Outbreak of hepatitis B associated with acupuncture. *J Fam Pract* 1986;22(2):155-8.
15. Walsh B, Maguire H, Carrington D. Outbreak of Hepatitis B in acupuncture clinic. *Commun Dis & Pub Health* 1999;2(2):137-40.
16. CDSC. Outbreak of hepatitis B associated with autohaemotherapy: update. *Commun Dis Rep CDR Wkly* 1998;8(13):113.
17. Ramsey ME. Guidance on investigation and management of occupational exposure to Hepatitis C. *Commun Dis & Pub Health* 1999;2(4):258-62.
18. Collinge J. Variant Creutzfeld-Jacob disease. *Lancet* 1999;354(9175):317-23.
19. Board of Science and Education of the British Medical Association. Acupuncture: efficacy, safety and practice. Amsterdam: Harwood Academic Publishers; 2000.
20. Department of Health. Immunisation against Infectious Diseases. London: HMSO; 1995.

Skin Disinfection and Acupuncture

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Summary

The need for skin disinfection before insertion of an acupuncture needle is controversial and there is no specific research on this topic. However research and observations on the effect of, and the need for, skin disinfection before injections forms a good analogy of acupuncture. Whilst micro-organisms present on the surface of the skin are accessible to disinfection, those located under the surface in ducts, glands and follicles are out of reach and can be inoculated into the sterile tissues below by needle insertion. Fortunately, the bacteria resident on the skin have a low potential to cause infection if host immunity is not severely impaired or compromised by the long-term presence of foreign material, such as a surgical stitch. Disinfection of clean skin before injection is not generally considered necessary and observations of lack of infection following injections without prior skin disinfection support this; however, contamination by micro-organisms not normally resident on skin can pose a higher risk of infection. If skin is visibly soiled, it should be washed and if needle insertion is near an infected or contaminated site, it should be disinfected with alcohol.

Practitioner hand hygiene between patients is important, even if gloves are worn. Hands should be washed with soap or detergent and water, or an alcohol handrub can be used if hands are physically clean.

Keywords

Acupuncture, skin disinfection, handwashing.

Introduction

The Microbiology of Skin

Skin is an inhospitable environment; it is dry, salty, acidic and there are few readily-available nutrients. The most fertile area of the skin is the outermost layer, but this surface is constantly being sloughed off and replaced by lower layers. An assortment of glands, follicles and ducts that go deep into the skin are also home to many microbes. As with many other microbial niches, competition between colonising species is severe and established species will exclude most potential newcomers.

Total bacterial counts on the skin's surface range from around 10 to 1,000,000 per square centimetre, but typically around 1,000. These bacteria are mostly present within microscopic colonies, typically composed of a few hundred bacteria, but which can contain up to 10,000 bacterial cells.¹ However, if the bacteria found in the ducts, glands and follicles below the skin's surface are taken into account by using a biopsy sampling method, the numbers recovered are around ten-fold higher than by sampling just the surface;² so most of the skin's microbial inhabitants are hidden from all but the most invasive of sampling methods. Passing a needle through the skin is thus one of the most searching methods of 'sampling' its microbial population.

Microbes on the skin can be divided into two groups: those that live and replicate on the skin, known as the skin's 'resident microflora', and those that are not long-term residents but whose presence results from recent contamination, termed 'transient microflora'.

The Resident Microbial Population

The skin's resident microbial population is, not unsurprisingly, one that has very little potential to cause infection ('pathogenicity'). The most pathogenic organism found on the skin is *Staphylococcus aureus*, one of the main causes of wound infection, but when colonisation does exist, it is usually confined to the nose and perineum. More widespread colonisation with *Staph. aureus* can be found with skin conditions such as psoriasis and eczema.¹ Normal skin is populated with coagulase-negative staphylococci (i.e. staphylococcal species other than *Staph. aureus*) and micrococci, a variety of coryneforms including propionibacteria and brevibacteria and a few gram-negative bacteria - acinetobacter and moraxella. These rarely cause infection, but can do so in situations where people's immunity has been compromised in some way, for example following surgery, burns, or insertion of indwelling foreign material such as surgical stitches.

The Transient Microbial Population

These skin contaminants will be located superficially on the skin unless they have been ground-in, such as bacterial spores following earth contamination during gardening or sport. When transient skin contaminants are superficially located, they are very readily lost by transfer on contact or washing. As they are acquired by touch, they are most commonly found on the hands. They can consist of anything at all; whatever was present on the last surface to be touched.

Skin Disinfection

Many different products are available under the general title of 'skin disinfectant'. (They are also referred to as antiseptics, meaning disinfectants compatible with living tissues). All skin disinfectants however are not the same and will be formulated to achieve one of three main functions:

Hygienic hand disinfection

This is where transient contamination is removed from the hands. This type of hand decontamination, where the main function is to

remove contamination acquired from previous patients, is highly appropriate to acupuncture practitioners. Contamination of a practitioner's hands with very small volumes of blood and serum can occur easily and is capable of transmitting infection. The most infectious of the blood borne viruses is hepatitis B which can be transmitted in 10 picolitres of serum (1 picolitre is 0.000 000 001 of a millilitre).³ The transfer of these minute volumes of serum from a patient's skin to a practitioner's hands and then to a subsequent patient's skin at an insertion point can occur quite easily. Scrupulous hand hygiene is needed to prevent the spread of such infectious agents. Gloves frequently develop holes during use and liquid contamination can actively travel through such holes by capillary action, so the wearing of gloves does not negate the need for hygienic hand disinfection. (Gloves must be changed between patients). Hygienic hand disinfection can be accomplished either by washing with soap or detergent and water, or use of an alcohol-based handrub is suitable. If hands are visibly soiled, they should be washed with soap or detergent and water; alcohol does not reliably penetrate organic, particularly proteinaceous, matter. Whatever the treatment, it has to be compatible with frequent use without damaging the skin.

Surgical hand disinfection

This is where transient contamination is removed, resident microflora are removed as far as possible and their re-growth inhibited for the duration of surgery. This is not relevant to acupuncture and is intended to suppress hand contamination that could be transferred into a surgical wound if glove puncture occurred during deeply-invasive surgery. This is traditionally accomplished by use of aqueous surgical scrubs which will remove transient and many resident microbes by detergent action and leave a microbicidal residue on the skin to discourage resident regrowth for some hours.

Patient preoperative skin disinfection

This is where transient contamination is removed,

resident microflora are removed as far as possible and their re-growth inhibited for the duration of the surgical dressing application. This is not relevant to acupuncture. It is accomplished by use of alcohol with an additional microbicide, repeatedly applied with friction for 3-4 minutes; the alcohol produces a high level of microbial kill, then evaporates, leaving a substantial residue of the microbicide (usually chlorhexidine) on the skin to discourage resident overgrowth for days in the 'greenhouse' environment (high moisture plus nutrients from the wound) under the dressing.

Skin Preparation before Acupuncture

None of the skin disinfection applications listed above are appropriate for pre-acupuncture patient skin preparation. The nearest analogous application is that of patient pre-injection skin disinfection, normally comprising a wipe with an alcohol-containing swab. The need for this category of skin disinfection and its effectiveness have both been questioned. The evidence, such as it is, that exists on these matters is outlined below.

The Aim of Pre-acupuncture Skin Preparation

The aim of pre-acupuncture skin preparation must be similar to that of pre-injection skin preparation, which itself is not as well established as the procedures given above. The reason generally given is to sterilise the skin and thus reduce the possibility of an infection resulting from the skin being pierced by a needle. Both the effect of skin preparation and the probability of an infection following skin penetration by a sterile needle are controversial.

The Microbicidal Effect of Skin Preparation

The agent normally used for preinjection skin preparation is alcohol, either as isopropanol or ethanol (usually as industrial methylated spirit) at a dilution of 70%; undiluted alcohol is a poor microbicide. Alcohol is the most appropriate agent for this function: it acts rapidly and has activity against all of the skin's resident microflora as well as most of the transient contaminants likely to be present. However it does have limitations. The

volatility of alcohol is both an advantage and a disadvantage; it evaporates quickly making it convenient to use, yet even a rapid disinfectant has little chance to act to its full potential in the ten to twenty seconds between application and evaporation. A five-second application of 70% isopropanol gives reductions of 82 to 91% upon sampling the surface of the skin.⁴

Many of the skin's microbial population are located under the surface, as was referred to earlier. This hidden microbial population will also be out of reach of any disinfectant used. The inability to truly sterilize skin was demonstrated in the same research in which cadaver skin was sampled by biopsy. None of the samples showed complete absence of bacterial growth after prolonged disinfection, and some types of skin, such as scalp and forehead, retained at least half their original bacterial colony-forming units.² Passing a needle, solid or hollow, through skin has much in common with biopsy sampling methods; the needle will come into contact with bacteria deep in the skin, out of reach of both disinfection and normal sampling methods, and move some of them further down the needle's path. Thus any claims that have shown living skin to be 'sterilised' must be regarded merely as failure to find microbes surviving the disinfection process under the skin's surface. However, in a survey of those giving injections in a UK hospital, over 50% gave 'sterilisation' as the reason they prepared skin prior to injection.⁵

Infection Following Sterile Needle Penetration

The possibilities of cross-infection, i.e. infection transmitted from other patients (due to failure of decontamination, or recontamination) or the practitioner (due to recontamination) are distinct and will not be considered in this section.

Even if disinfection does not truly sterilise the skin, does the microbial reduction it produces significantly reduce the possibility of an infection after skin piercing? Is there a significant risk of infection following skin penetration by a sterile needle?

The most likely bacterial species to cause infection following sterile needle penetration is

Staph. aureus, an occasional inhabitant or contaminant of skin (see the section on the skin's resident microbial population above). In an unusual set of experiments in the 1950s (it is highly unlikely they could be repeated ethically today), volunteers were injected with cultures of abscess-derived *Staph. aureus*.⁶ Only injection of high numbers, around 7,500,000 organisms, produced infection at the inoculation site.

Looking at these results in the context of acupuncture and in the unlikely event that there were significant numbers of *Staph. aureus* on the skin, the following calculation can be derived. Assuming an acupuncture needle of 0.29mm (which would have a cross-sectional area of 0.066mm² and skin with a maximum bacterial population of around 1,000,000 cm⁻², or 10,000mm⁻²; if the needle produced inoculation of skin equivalent to its whole cross-section (a generous assumption), on average 660 bacterial cells would be pushed into the skin by an acupuncture needle. Even if the acupuncture needle hit a large microcolony and pushed it all into the skin (another generous assumption), this would be a maximum of around 10,000 organisms. This calculation shows infection from an acupuncture needle passing through normal skin of an individual without compromised immunity to be a very remote possibility.

The factor found to enhance infectivity was to introduce the staphylococci on a suture which was then left in the skin, in which case around 100 organisms could produce an infection.⁶ However, when around 2,400 *Staph. aureus* were deposited in the skin by drawing a contaminated suture through the skin but not leaving it in place, no infection resulted. It was concluded that it was the long-term presence of a foreign body that compromised host defences, rather than it acting as a vehicle for the inoculum. This seems to justify patient preoperative skin disinfection but not pre-acupuncture or pre-injection skin preparation.

Observations in Practice

The origins of skin prepping before injection, the nearest analogy for pre-acupuncture skin

preparation, are unclear but it seems safe to assume that it was thought to be general good practice. There is no record that it was prompted by observation of post-injection infections. The first record of this ritual being questioned is in 1962 by the Ministry of Health in its Memorandum on Vaccination Against Smallpox by noting⁷, after advising that alcohol could be used on the vaccination site, "*Many doctors use nothing at all if the arm is reasonably clean and there is no evidence to condemn this practice*".

This was followed by a university Medical Officer, TC Dann, who abandoned skin preparation before injections unless the skin was obviously dirty. Over the course of six years, his department gave over 5,000 injections to students, all types of university staff (not just academic staff) and their families (age range 4 months to 66 years). No resulting infections were observed.⁸ A letter in response to this publication supported lack of observed infection following thirty years of injections without prior skin preparation both in the UK and in a Himalayan population "which had never washed since birth".⁹ However in both of these studies, no details of structured follow-up observations to observe complications are given. There has been a small trial of alcohol swab (93 patients) versus no pre-treatment (103 patients) before venesection, with follow-up observations at 1, 3 and 5 days.¹⁰ Although two patients developed an abscess at the venesection site (both of these were in the alcohol swab group and both were on long-term steroid therapy), there was no statistically-significant difference between the two groups.

There is some authoritative recommendation on the matter of skin preparation. The Martindale pharmacopoeia,¹¹ published by the Royal Pharmaceutical Society, on the topic of disinfection of injection sites, states:

The need to disinfect the skin before injection is controversial. Routine skin preparation of the injection site has been reported to be both ineffective and unnecessary.

The Public Health Laboratory Service, in its publication *Chemical Disinfection in Hospitals*,¹² states:

The necessity to disinfect the site with 70% ethanol or 60 - 70% isopropanol prior to injection is controversial. There is evidence that giving an injection without prior cleaning is not associated with increased infection risk in young, healthy individuals and it is not recommended for routine insulin injections in diabetic patients because of potential damage to the skin. Some hospitals have given up the use of alcohol before giving injections and no adverse effects have been reported. It is still used (usually with chlorhexidine) before cannulation procedures, intra-articular injections and taking blood cultures. However, disinfection of the injection site continues to be used in most hospitals, particularly for injections into the thigh, and in elderly or immunocompromised patients, or close to infected or colonized lesions. The area should be wiped thoroughly and allowed to dry before giving the injection. This will remove or kill most transient organisms.

Although changes in skin preparation policy are rarely made public, there are exceptions. In 1985 Nottingham City Hospital reported that:

*Skin preparation before intramuscular and subcutaneous injections has been discontinued without any adverse effects.*¹³

Other hospitals have introduced similar changes, but without such announcements. One such reported that it can be difficult to interrupt a well-established ritual; eight years after a policy decision to cease routine pre-injection skin

swabbing, 78% of staff surveyed at a UK hospital continued the practice. The main reason given by those continuing was 'sterilisation' (52%).⁵

Reference list

1. Noble WC. *Microbiology of Human Skin*. 2nd Edition. 1981. Lloyd-Luke, London.
2. Selwyn S, Ellis H. Skin bacteria and skin disinfection reconsidered. *BMJ* 1972;1(793):136-140.
3. Feinman SV, Berris B, Guha A, Sooknanan R, Bradley DW, Bond WW, Maynard JE. DNA:DNA hybridization method for the diagnosis of hepatitis B infection. *J Virol Methods* 1984;8(3):199-206.
4. Kovisto VA, Felig P. Is skin preparation necessary before insulin injection? *Lancet* 1978;1(8073):1072-1073.
5. Liew J, Archer GJ. Swabholics? *Lancet* 1995;345(8965):1648.
6. Elek SD, Conen PE. The virulence of *Staphylococcus aureus* for man. A study of the problems of wound infection. *Br J Exp Pathol* 1957; 38(6): 573-586.
7. Ministry of Health. *Memorandum on Vaccination Against Smallpox*. 1962. HMSO, London.
8. Dann TC. Routine skin preparation before injection: An unnecessary procedure. *Lancet* 1969;2(7611) 96-98.
9. Turner RWD. Skins and needles. *Lancet* 1969;2(7618):490-491.
10. Sutton CD, White SA, Edwards R, Lewis MH. A prospective controlled trial of the efficacy of isopropyl alcohol wipes before venesection in surgical patients. *Ann R Coll Surg Engl* 1999;81(3):183-186.
11. Martindale. *The Complete Drug reference*. 32nd Edition 1999. The Pharmaceutical Press, London.
12. Ayliffe GAJ, Coates D, Hoffman PN. *Chemical Disinfection in Hospitals*. 2nd Edition 1993. Public Health Laboratory Service, London.
13. Anon. *Nursing Times* (Journal of Infection Control Nursing) 1985;81(35):suppl.14.

Safety Aspects of Acupuncture in Palliative Care

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Summary

Acupuncture can mask symptoms of cancer and tumour progression. It is not safe to use such a therapy without full knowledge of the clinical stage of the disease, and the current status of orthodox therapy. Contraindications to acupuncture needling include an unstable spine, severe clotting disorder, neutropenia and lymphoedema. Whilst semi-permanent needles are used increasingly in symptom control and pain management they should not be used in patients with valvular heart disease or in vulnerable neutropenic patients. Acupuncture has an increasing role in support for pain and symptom management, but patients should not be advised to abandon conventional treatments in favour of complementary or alternative therapies alone, and should not have their hopes raised inappropriately, or have any guilt projected on to them for the cause of their cancer.

Keywords

Acupuncture, palliative medicine, adverse events, safety.

Introduction

Complementary and alternative medicine (CAM) is enjoying increasing popularity amongst the general public and cancer patients are no exception. Its use for cancer pain has been reviewed and includes some of the following data:¹ In a review of 26 surveys of the use of CAM by cancer patients in 13 different countries the use varied from 7-64%, with an average of approximately 30%.² In children, the frequency was up to 50%, with patients often using multiple

therapies. One hundred and forty-one health care professionals in Ontario, working with cancer patients, were asked to identify which pharmacological therapy, out of a choice of 19, they would like to learn more about. Of the top 5, acupuncture/acupressure was the foremost choice,³ followed by massage, hypnosis, 'therapeutic touch' or healing and biofeedback.

The main reasons that patients turn to CAM have been explored,^{4,5} but the plain fact is that orthodox medicine cannot reliably deliver a cure for many symptoms and conditions. The need for self-empowerment and ability to cope, both physically and emotionally, attracts patients to therapies often perceived as gentle, and natural, with fewer side effects than conventional treatment.

The attitudes of the medical, nursing and allied health professions are progressing from antagonism to amicable coexistence. There is increasing acceptance of therapies that have efficacy in the areas of symptom control, for example, nausea and vomiting, xerostomia, dyspnoea, pain, and anxiety. There is also increasing acceptance of a multiplicity of mind body therapies that help patients adopt a positive approach and improve their quality of life.

The incidence of cancer is rising in the UK, where it is responsible for approximately 25% of all deaths per year. The commonest cancers are breast, lung, gut, prostate and skin. Treatment is ideally preventive, through education about the risks of, for example, smoking and use of sunscreens, and the benefits of, for example, healthy eating. Treatment can also be therapeutic. Cancers are locally invasive and many metastasise

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to other sites, through loco-regional spread, especially to lymph nodes, but also through distant spread, to bone, lung, brain and liver. Bone metastases are particularly common in cancers of the lung, breast, prostate, thyroid and kidney. A reasonable knowledge about the types of cancer and their therapeutic options, including surgery, chemotherapy, hormone therapy and biological therapies, is necessary before treating these patients. Cancer treatments are continually evolving, and current treatments are based on a combination of scientific research and clinical trials. Knowledge of the subject, therefore, needs continuous updating.

Pain in a cancer patient may be related to the primary disease, metastatic disease, the cancer treatment, or it may be unrelated. Common sources of cancer related pain include bone pain, nerve pain, soft tissue infiltration, visceral pain and myofascial pain. Multiple pains with multiple aetiologies may exist in the same patient. It is important to fully assess each symptom prior to treatment.

Acupuncture in the cancer patient

Direct effects of acupuncture

Acupuncture has an increasing part to play in the treatment of cancer pain and symptom management.^{6,7} It is not uncommon to have unexpectedly welcome side-effects, such as the disappearance of long standing psoriasis, migraine, gastrointestinal problems, or symptoms

of prostatism. Acupuncture can, however, mask a serious problem, or disease progression, so the clinical condition needs continuous monitoring alongside the oncology team treating the patient. As a consequence, acupuncture treatment in cancer patients should ideally be given by, or closely supervised by, a physician who is knowledgeable about the clinical staging and current treatment of their patients.

It is regrettable that, despite numerous papers describing largely observational work in palliative care patients, specific side effects, including aggravation of symptoms, have not often been mentioned. Blom et al mentioned bleeding and tiredness post-treatment.⁸ Rydholm and Strang specifically looked for infection and haemorrhage in 20 late-stage palliative care patients and found neither.⁹ The multiple acupuncture treatments for advanced cancer related pain were very time consuming for the practitioners, Wen, 1977¹⁰ and the short-lived relief not thought to be practical by Mann, 1973.¹¹ Informal recommendations based on papers and chapters plus clinical practice remains for the moment the best sources of advice on this topic.

Table 1 shows a list of contraindications to acupuncture treatment in cancer patients.

Acupuncture is contraindicated around an unstable spine, in case the removal of protective muscle spasm causes spinal cord transection.¹² Patients with multiple myeloma are particularly vulnerable, and the use of transcutaneous

Table 1 Contraindications and Cautions

Contraindications

- Do not needle in the local area of an unstable spine – this could lead to spinal cord injury or transection
- Do not directly needle superficial tumour nodules or ulceration
- Avoid needling a lymphoedematous limb
- Avoid needling if blood clotting is seriously impaired
- Do not needle into a prosthesis
- Do not needle intracranial deficits
- Avoid electroacupuncture in patients with a demand pacemaker

Cautions

- Cancer patients can be more sensitive to acupuncture, and nursing assistance is recommended for each case
- Take great care with needling depth in cachectic patients, especially over the chest wall
- If tolerance occurs it may represent progressive disease and full investigation of tumour status is advised

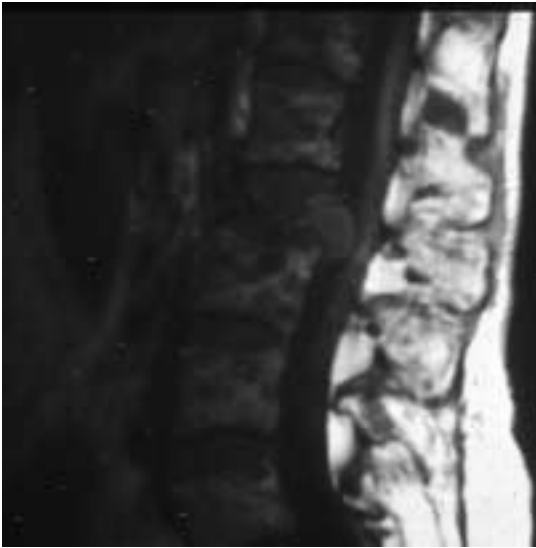


Figure 1 This lateral spine radiograph shows extensive tumour deposits from multiple myeloma. Acupuncture should not be used in the vicinity of any areas of instability.

electrical nerve stimulation (TENS) may be a safer option, paravertebrally near the site of instability. There are no published case reports of spinal transection following acupuncture treatment of the spine in cancer patients, but the author has collected numerous 'anecdotes', albeit low level evidence, over the years. For example, one patient with metastatic breast cancer, who had complete pain relief from back pain following acupuncture treatment, subsequently suffered a spinal transection ten days later at home. Unfortunately, no specific details are available. Another patient with multiple myeloma experienced an increase in neurological symptoms, accompanied by band-like pain, shortly after acupuncture treatment. The patient had already had one operation to stabilise the spine internally, and was not expected to suffer any more spinal instability in that region of the spine. Figure 1 shows the moth-eaten spine of a patient with multiple myeloma. This patient would be vulnerable to spinal cord transection at a number of spinal levels.

Acupuncture is a very profound muscle relaxant. Patients with metastatic disease around the cervical spine often exhibit excessive muscle spasm in the muscles that hold the head in an

upright position. The muscles involved in supporting the lower back may also be in extreme spasm in an effort to maintain stability in patients with lower spinal instability. This is not necessarily immediately obvious on external examination. As a consequence, it would be prudent not to needle around an unstable spine, and to use TENS as a suitable non-drug alternative. In more recent years, the employment of bisphosphonates, such as clodronate and pamidronate, have decreased the incidence of pathological fractures due to bone metastases, particularly from breast cancer and multiple myeloma.¹³ Reliance on traditional Chinese energetic diagnosis alone could be potentially dangerous in this type of patient.

Superficial tumour nodules or skin ulceration should not be directly needled, since this may



Figure 2 This figure shows a grossly lymphoedematous arm with serous fluid leaking from the axilla. Acupuncture is contraindicated in such a limb, due to the risk of cellulitis.

result in an increased likelihood of local or distant spread.

Needles should not be inserted in a limb with lymphoedematous swelling¹⁴ (figure 2). Broken skin is a source of potential infection and cellulitis, and the patient could continue to ooze fluid from sites of needle insertion. For the most part, acupuncture treatment, even at distant sites, does not improve lymphoedema. On occasions, however, the author has seen a dramatic reduction in swelling by as much as 30-50% following treatment, with the needles inserted proximal to the lymphoedematous limb, a most welcome side effect!

Blood clotting is commonly compromised in patients with leukaemias and other haemato-oncological disease. Clotting dysfunction is a frequent accompaniment to many types of chemotherapy and is extreme following bone marrow transplantation, either allograft or autograft. A platelet count of over 20,000 is preferable and caution needs to be exercised in patients anticoagulated with warfarin. In many cases the results of clotting tests are unavailable, so it is inadvisable to give acupuncture to any patient whose clotting function is moderate or severe, or to one who bleeds and bruises spontaneously, or to one with multiple petechiae.

One should not needle into a prosthesis, e.g. a breast implant after a latissimus dorsi flap reconstruction. Needling may result in leakage from the implant or infection around the capsule. One should not needle directly over an intracranial deficit following neurosurgery. Needling may cause infections, such as meningitis, or could result in intra-cranial haemorrhage.

Cancer patients may appear to be more sensitive to acupuncture than other patients, and

may become excessively sleepy even after very short acupuncture treatments. It is inadvisable to treat them without nursing assistance. All patients should be given very gentle treatments initially, and subsequent treatments should be tailored to the individual, based on their responses. Cachectic cancer patients should be needled only very superficially. If tolerance occurs in a cancer patient it may be due to disease progression and the patient may need further investigation.

Of 25 patients who become tolerant to acupuncture, 17 were subsequently diagnosed to have metastatic spread, sometimes pre-clinical detection.¹⁵ If a patient becomes tolerant after previously responding well, it is reasonable to suggest restaging of that patient in case of recurrent disease. Interestingly, following treatment of any cancer metastasis, such patients often resume being responsive to treatment.

Acupuncture is increasingly used as an adjunct to cancer surgery for 'acute pain' management. It is advisable to secure the needles safely preoperatively and to record the number of needles inserted on a white/blackboard, much like a swab count, ensuring that the needle number is checked very carefully at the end of the case to avoid leaving unwelcome 'souvenirs' in the patient postoperatively.

Direct effects of semi-permanent needles

Semi-permanent needles are now used quite extensively in advanced cancer related dyspnoea,^{6;16} anxiety,⁷ pain,^{17;18} and treatment of disabling hot flushes due to hormone therapy for breast¹⁹ and prostate cancer (personal observation). Contraindications and cautions are outlined in Table 2.

Do not use if the patient has heart valve disease, a pacemaker, or a post cardiac transplant. There is

Table 2 Contraindications and Cautions for the Use of Semipermanent Needles in Cancer Patients

Do not use in patients with valvular heart disease
Do not use in neutropenic patients
Post-splenectomy
Avoid in patients with known hepatitis B or C due to risk from needle stick 'fall out'
'Strong reactors'
Caution in patients with keloid scars

a chance of infection, e.g. subacute bacterial endocarditis.

Post-splenectomy patients are relatively immunocompromised, and it makes sense to take care with, and possibly avoid the use of, semi-permanent needles in these patients.

Avoid their use in patients with known hepatitis B and C. If a semi-permanent needle were to 'fall out' it could represent a risk of needle stick injury to others.

'Strong reactors' to acupuncture are unfortunately too sensitive to have semi-permanent needles left in situ, so they need to have their treatment maintained by intermittent 'top ups'.

It may be a relative contraindication to treat patients prone to keloid formation.

Semi-permanent needles should not be inserted in patients during cycles of chemotherapy or radiation treatment, as the needle is a potential source of infection, and patients are, at these times, vulnerable to develop life-threatening sepsis, especially if the white cell count is low and the patient profoundly neutropenic. Any severe immunosuppression from any cause is in fact a contraindication to the use of semi-permanent needles, and this consequently includes many patients in the intensive care unit.

Needles that 'fall out' could represent a sharp hazard. It is not always clearly stated in the literature what happens to the needles when they fall out.^{17:18} It is possible that it may not always be known.

Side effects to indwelling studs for palliative care have not been formally audited, but in my own practice they include redness and soreness on occasions, pain and discomfort around the site, and slight thickening in a patient who gets keloid scars. I have seen occasional reactions to the clear plastic dressings that are placed over the studs to decrease the chance of accidental loss of the needles.

Do it yourself (DIY) needle kits are becoming commonplace for outpatient maintenance of symptom control, such as hot flushes associated with tamoxifen therapy. It is essential that patients

provided with these are given clear instructions for their use, including skin cleansing prior to insertion, and that they are given suitable containers for safe disposal, and transport back to the clinic, of used needles.

Indirect effects of acupuncture

Patients should be advised not to abandon conventional treatment in favour of any alternative treatment. This can happen in centres for CAM, often with limited medical input, and perhaps by well intentioned individuals. Patients should not be given false hopes by practitioners, or have any guilt projected on to them regarding the cause of their cancer.

Inappropriate advice about the effects of a treatment on the cancer, or on life style, can be risky, especially if acupuncture and other complementary medical treatments are offered as an alternative to conventional anticancer treatment. Pain and suffering are not separate, but are closely intermingled. Anger and denial about cancer are common in patients, and the sensitive handling of such patients requires considerable skill and specialised counselling, with the addition, in many cases, of formal psychological support. Inappropriate advice can also be exceedingly emotionally damaging. Financial exploitation can occur in these patients, and prolonged courses of treatment are sometimes given inappropriately.

The lack of understanding of the cancer process and treatment can be a handicap, and remission may be seen as a cure by well meaning practitioners who are inexperienced in treating this type of patient. The author has unfortunately and sometimes tragically seen all of these complications, plus the masking of diagnosis and disease progression, with a consequent delay in appropriate treatment.

Conclusion

The beneficial effects of treatment for cancer pain and symptom control generally appear to outweigh the negative side effects of acupuncture treatment in the cancer population. The use of

acupuncture for symptom control in palliative medicine can be one of the most rewarding aspects of medical care, when used appropriately. However, there is also significant potential for serious adverse events. A prospective study of side effects to more accurately identify the risks in this population would be ideal. This would represent a huge organisational task, but given the vulnerability of the patients and theoretical dangers, this is a task that urgently needs to be performed.

Reference List

1. Filshie J, White A. Complementary Therapies for Cancer Pain. In: Sykes N, Fallon M, editors. *Clinical Pain Management*. London: Edward Arnold; 2002.
2. Ernst E, Cassileth BR. The prevalence of complementary/alternative medicine in cancer: a systematic review. *Cancer* 1998;83(4):777-82.
3. Sellick SM, Zaza C. Critical review of 5 nonpharmacologic strategies for managing cancer pain. *Cancer Prev Control* 1998;2(1):7-14.
4. Cassileth BR, Brown H. Unorthodox cancer medicine. *CA Cancer J Clin*. 1988;38(3):176-86.
5. Cassileth BR, Chapman CC. Alternative cancer medicine: a ten-year update. *Cancer Invest* 1996;14(4):396-404.
6. Thompson JW, Filshie J. Transcutaneous Electrical Nerve Stimulation (TENS) and Acupuncture. In: Doyle D, Hanks G, MacDonald N, editors. *Oxford Textbook of Palliative Medicine*. Oxford: Oxford University Press; 1998. p. 421-37.
7. Filshie J. Acupuncture in palliative care. *Eur J Palliat Care* 2000;7(2):41-4.
8. Blom M, Dawidson I, Angmar-Mansson B. The effect of acupuncture on salivary flow rates in patients with xerostomia. *Oral Surg Oral Med Oral Pathol* 1992;73(3):293-8.
9. Rydholm M, Strang P. Acupuncture for patients in hospital-based home care suffering from xerostomia. *J Palliat Care* 1999;15(4):20-3.
10. Wen HL. Cancer pain treated with acupuncture and electrical stimulation. *Mod Med Asia* 1977;13(2):12-6.
11. Mann F, Bowsher D, Mumford J, Lipton S, Miles J. Treatment of intractable pain by acupuncture. *Lancet* 1973;2:57-60.
12. Filshie J, Redman D. Acupuncture and malignant pain problems. *Eur J Surg Oncol* 1985;11(4):389-94.
13. Diel IJ, Mundy GR. Bisphosphonates in the adjuvant treatment of cancer: experimental evidence and first clinical results. International Bone and Cancer Study Group (IBCG). *Br J Cancer* 2000;82(8):1381-6.
14. Mortimer PS, Badger C, Hall JG. Lymphoedema. In: Doyle D, Hanks GWC, MacDonald N, editors. *Oxford Textbook of Palliative Medicine*. Oxford: Oxford University Press; 1998. p. 657-65.
15. Filshie J. Acupuncture for Malignant Pain. *Acupunct Med* 1990;7(2):38-9.
16. Filshie J, Penn K, Ashley S, Davis CL. Acupuncture for the relief of cancer-related breathlessness. *Palliat Med* 1996;10(2):145-50.
17. Dillon M, Lucas CF. Auricular stud acupuncture in palliative care patients: an initial report. *Palliat Med* 1999;13(3):253-4.
18. Alimi D, Rubino C, Leandri EP, Brule SF. Analgesic effects of auricular acupuncture for cancer pain. *J Pain Symptom Manage* 2000;19(2):81-2.
19. Towlerton G, Filshie J, O'Brien M, Duncan A. Acupuncture in the control of vasomotor symptoms caused by tamoxifen. *Palliat Med* 1999;13(5):445.

Informed Consent for Acupuncture - An Information Leaflet Developed by Consensus

Adrian White, Mike Cummings, Val Hopwood, Hugh MacPherson

Summary

Patients have the right to be fully informed about the likely benefits and risks of any proposed examination or treatment, and practitioners are obliged to obtain informed consent beforehand. Accurate information about the risks of acupuncture is available following publication of the results of two prospective surveys. At a joint meeting on the safety of acupuncture, members of the three largest UK professional bodies expressed a need to establish what information on risks patients should be given. A standard Information Leaflet was developed by consensus between these organisations, and is intended to be used as a stimulus for discussion of standard risks as well as any particular risks that might apply to individual patients. Additionally, it may be used as a form for written consent when this is required. To provide the context for using the Leaflet, the legal and ethical bases of informed consent for medical procedures are discussed.

Keywords

Acupuncture, informed consent, consensus, information leaflet.

Introduction

Acupuncture is increasingly used by health professionals in the UK, both within and outside the health service. As with all treatments, patients have the right to be fully informed about the likely benefits and risks, and practitioners are obliged to obtain informed consent beforehand. This paper will address the question of risks not benefit, since the benefits cannot be discussed in a standardised way. Currently, informed consent for acupuncture treatment is usually an informal matter. In other

words, most acupuncture practitioners probably provide information on the risks of acupuncture only when they are asked, and consent is assumed by the fact that the patient has turned up at the clinic and undresses in preparation for treatment. While this approach might reflect much of current practice, it is timely to reassess procedures in the light of recent research on safety, current legal opinion and developments in ethical practice. In meeting patients' rights, a balance should be struck between the informality that can engender a positive therapeutic environment and the formality in meeting ethical and legal requirements.

Patients have the fundamental right to be allowed to give consent to treatment; 'Respect for bodily integrity and privacy are values that are central to any theory of consent'.¹ One of the prime principles of ethical behaviour between practitioners and their patients is patient autonomy. This is also becoming increasingly a legal principle, and Human Rights legislation has been introduced as the basis of case law in the UK (Human Rights Act 1998, put into force in October 2000). Much case law governing medical practice predates this human rights legislation, so practitioners will remain somewhat in the dark until new cases are decided. Nevertheless, patients are entitled to best practice and practitioners need guidance now. It is therefore timely that the Department of Health recently issued a guide to informed consent based on the current legal opinion.² This is necessarily a 'catch-all' document that has been designed to be applicable to extreme situations that often bear little relationship to practitioners providing routine acupuncture to patients who have asked for treatment. Nevertheless, practitioners should be aware of the underlying principles as a firm basis for their actions. The

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authors of the Department of Health document are able to give detailed advice on every area of informed consent except, unfortunately, the crucial matter of 'disclosure of risk'. In other words, it is clear that patients have a right to be given relevant information before they decide to receive treatment, but it is not yet clear how to decide precisely what information is relevant.

While the question of which risks patients should be told about is still undecided, at least we can now be much clearer about what risks acupuncture actually poses, since the publication of two prospective surveys.^{3,4} For the first time, discussion of the risk of acupuncture can be based on evidence rather than on clinical impression. All three major professional acupuncture organisations in the United Kingdom were involved in collecting the data for these surveys, and in celebration of this unanimity of purpose, a special joint conference on safety was held in June 2001. The conference delegates made a clear call for a standard information sheet on the risks associated with acupuncture treatment. It was agreed that the three registration bodies (the Acupuncture Association of Chartered Physiotherapists, the British Acupuncture Council and the British Medical Acupuncture Society) would be responsible for developing and agreeing this information sheet. This was achieved by meetings and email discussions among the authors representing their respective bodies, together with peer review by senior members from each organisation.

This article presents the standardised Information Leaflet agreed by this consensus procedure. Additionally, it summarises the formal legal background to situations that are most likely to be met in acupuncture practice, while accepting that patients should not be subjected to unnecessary formalities and that it is vital to maintain a common sense approach.¹ Readers who require more detail or information on other specific situations are advised to refer to the original sources.^{2,5} In particular, the special conditions which apply to obtaining consent for video or sound recordings and to clinical trials are not dealt with here.

The legal and ethical background

The recent literature sources on informed consent on which this article is based are an editorial article,¹ the Department of Health website,² the guide on informed consent published by the General Medical Council (GMC),⁵ and an information sheet currently in use in a German academic acupuncture clinic.⁶ The Department of Health guide is based on current case law and legal opinion, whereas the GMC guide, produced by a professional body, also considers the ethical issues and as a result is in some respects more demanding.

Before examining, treating, or caring for competent adult patients, their informed consent must be obtained. In the normal practice of acupuncture, this will involve the practitioner giving appropriate information on benefits and on risks (for example, in the Information Leaflet, see Appendix A) and the patients implying consent by preparing themselves for treatment (e.g. by undressing and climbing on the couch). These procedures are clearly relatively informal, but they must be routinely applied.

Although normal practice relies largely on common sense, patients are ultimately protected by the law. This only comes into play in unusual circumstances or when things go wrong. Theoretically, any health professional who does not respect the principle of informed consent may be liable both to legal action by the patient and to action by their professional body. Touching a patient without valid consent, for example, may constitute the civil or criminal offence of battery. Further, if health professionals fail to obtain informed consent and the patient subsequently suffers harm as a result of treatment, this may be a factor in a claim of negligence against the professional.

Students are subject to additional requirements. If a student is using examination or treatment as part of the learning process, additional consent must be obtained. This additional consent is no longer a legal requirement once the student has been trained to carry out a procedure which forms part of the patient's normal care, though it is still good practice to tell the patient.

The key principles of informed consent are that

consent must be given by a patient

- a) voluntarily,
- b) who has the capacity to understand and
- c) who has been given appropriate information.

In respect of a) voluntariness, this means without any pressure or undue influence from family, friend or health professional. The use of acupuncture against the patient's wishes, for example in patients who are detained against their will, is an exceptional circumstance and is not considered here. In respect of b), the capacity to understand, patients must be able to understand and retain the information given and use it in forming a judgement. Adult patients are assumed to be competent unless proven otherwise; the procedure of acupuncture is relatively straightforward and few people will find it hard to understand. Apart from the special case of minors (see below) the question of the patient's competence is unlikely to arise in normal clinical circumstances relating to acupuncture. Special considerations apply to obtaining consent from adults and children who do not have the capacity to give informed consent (see DoH website²).

The matter of what is c) 'appropriate information' is not clearly defined and may be open to judgement. There are some principles to guide the practitioner. Patients must understand in broad terms the nature and purpose of the procedure. The duty of care also demands that patients should also be informed about any alternative treatments that may be available, and their benefits and risks. Deciding what information to provide was previously subject to the 'Bolam' test; in other words, the practitioner must do what conforms to a responsible body of medical opinion. However, this principle has subsequently been changed by case law (the Sidaway case⁷). The House of Lords ruled that the courts can decide that information about a particular risk is so obviously necessary that it would be negligent not to provide it, even if a 'responsible body' of professional opinion would not have done so. The courts will probably consider that it is necessary to inform the patient of any 'material' or 'significant' risks in the proposed treatment, any alternatives to it, and the

risks incurred by doing nothing.² It is also the responsibility of the clinician to inform a patient of 'a significant risk which would affect the judgement of a reasonable patient', even if this would lead to the patient declining treatment. The GMC guide adds the ethical demand that doctors should do their best to find out about patients' individual needs and priorities when providing information. In the very rare event that such information is withheld by the clinician on the grounds that it would be deleterious to the patient's health, this should be recorded in the notes. This decision by the practitioner needs real clinical justification - not just that the patient would be upset or might refuse treatment. Occasionally patients do not wish to know much about their treatment and will decline the offer of information, in which case this should be recorded in the notes. Any misrepresentation of information will invalidate the consent.

Who should provide information and obtain consent? Usually this will be the clinician, but acupuncture is practised in a variety of circumstances. For example, an anaesthetic consultant in a Pain Clinic may refer a patient to an acupuncturist in the clinic, who is assisted by nurses. It is the responsibility of the acupuncturist providing treatment to ensure that the patient has given valid consent before the treatment begins. However, the actual process of obtaining consent may be delegated to the nurses provided that they have sufficient knowledge of the procedure.

Consent may be given in writing, verbally, or by implication. The question arises whether the patient's signature should be obtained routinely before acupuncture. The answer in most cases is 'No' since informed consent is not made valid simply because the patient signs a form. The clinician must be certain that the information has been understood, retained and applied in reaching the decision. Consent can be implied from an appropriate action, e.g. climbing on to a treatment couch. Acupuncturists should be particularly sensitive to any hesitation by patients who may be overwhelmed by the strangeness of the procedure and unable to express their concerns. In such cases, it is recommended that explicit verbal

consent be obtained. The GMC and the Chartered Society of Physiotherapy suggest that, if doctors or physiotherapists do not use a consent form before conducting a procedure, they should record in the patient's notes the fact that consent was given, and the main details of the discussion.

Consent only covers the procedures that have been explained, so fresh consent should be obtained to cover any additional procedures that become necessary during the treatment. In the context of acupuncture, it seems likely that this would apply to interventions such as electroacupuncture and moxibustion.

Refusal to give consent must be respected, although it would be unusual for someone who requests acupuncture treatment to refuse consent. However, limited refusal may occur, such as patients who decline to have treatment to certain areas of the body. When consent is given it generally remains valid for an indefinite duration unless withdrawn. If new information (e.g. about the effectiveness of alternative treatment options) becomes available during a course of treatment, the GMC suggests that the clinician should tell the patient. Patients have the right to withdraw consent at any time, even during the procedure.

People aged 16 or 17 are entitled to give or refuse consent for their own medical treatment under the same terms as for adults. Although refusal may be overridden (by either a person with parental responsibility or by a court) it seems unlikely that any acupuncturist would proceed with treatment under these circumstances. While it is not strictly necessary to obtain consent from the parents as well as from the young person, it is good practice to do so unless the latter specifically does not wish this.

In the case of children below the age of 16 years, the concept of 'Gillick competence' applies. This means that children who have sufficient intelligence and capacity to understand what is involved in the proposed treatment will also have the capacity to give consent. The capacity to understand may vary with different medical or surgical procedures. Since it is relatively easy to understand what acupuncture treatment involves, it seems probable that even quite young children

should be involved in giving consent. It is important that this consent is given voluntarily and not under any influence of parents or other carers. If a Gillick competent child refuses consent, the parent may overrule them, for example if the child is at risk of 'grave and irreversible mental or physical harm', though this seems unlikely in clinical situations involving acupuncture.

Recommendations

After discussion, the authors agreed that patients who wish to undergo acupuncture treatment should be informed of the risks in four categories, and these are included in the Information Leaflet. Leaflets with (Appendix A) and without (Appendix B) integral consent statement are presented.

Risks for which the evidence indicates an incidence of 1% or greater, even though none of these risks could truly be considered 'material' or 'significant'. This recommendation errs on the side of caution, since the authors of a recent survey argued that 'minimal' risks need not be discussed unless the patient specifically asked.⁴ However, patients have varying expectations of acupuncture, and, for example, some even express surprise that acupuncture points bleed.

Certain other risks that were judged to be 'material' or 'significant', even though very rare. These include the risk of drowsiness, which affects road users.

Risks associated with particular clinical situations that apply in an individual patient. In order to reduce these risks, patients should give relevant information such as bleeding abnormality or pregnancy. This category also includes specific risks such as bacterial endocarditis with indwelling needles in patients with damaged heart valves. Sometimes the risk may be revealed only at the time of clinical examination, such as risk of pneumothorax in patients with thin chest walls and diseased lungs, for example in chronic bronchitis, emphysema or bronchiectasis. Discussion of these risks can be accompanied by specific advice to the patients on recognising adverse events when they arise.

Serious adverse events. Evidence from recent surveys indicate that these are very rare in

acupuncture. Patients should be informed that serious side effects do occur but the risk is minimal i.e. the incidence less than one per 10,000 treatments.

The order and wording of the Leaflet were carefully framed to give all required information truthfully and without misrepresentation, yet attempting to avoid inducing anxiety in the reader. The form is designed to be used either as an 'aide memoir' to the practitioner who is giving information when obtaining consent, or to be read directly by the patient before discussion with the practitioner (or, occasionally, another person who is knowledgeable on the subject). One version of the Leaflet includes space for the patient's signature. The general recommendation regarding obtaining the patient's signature is that it is not normally necessary, although health service trusts and other employers might require it. Merely reading the form, even if accompanied by a signature, may not be taken as evidence that the patient has fully understood the risks. It is the practitioner's responsibility to ensure the latter, although no advice on how was offered in our information sources.^{2,5} We believe that it would be insufficient, for example, simply to ask the receptionist to hand the consent form to patients in the waiting room for signature without any opportunity to discuss it with the practitioner.

Since treatment of children under 16 with acupuncture is relatively uncommon, no specific facility was added for signed parental consent for this group.

Comments

We recommend that the process of obtaining informed consent for acupuncture treatment under normal circumstances should be carefully reconsidered by all practitioners. As well as learning the potential benefits of treatment, we recommend that practitioners should explicitly discuss some of the risks of treatment. We do not recommend obtaining signed consent, but regard patient consent as sufficient if it is implied, e.g. by their climbing on the couch.

While these recommendations are based on good ethical practice, they are as yet limited in the sense that they are based on legal opinion rather

than actual case law. On the basis of recent research, Vincent concluded that 'acupuncture is a very safe intervention in the hands of a competent practitioner'.⁸ We therefore take the position that the 'material' and 'significant' risks of acupuncture treatment given by trained and competent practitioners are minimal. Another issue which we have highlighted here is how the clinician needs to ensure that the patient has fully understood all of the risks and taken them into consideration in giving consent. We accept that some acupuncture practitioners will feel constrained by these recommendations, but this article arose in response to a need expressed by the majority of practitioners who attended the safety conference.

Whilst the Information Leaflet has already received wide review, it must be considered provisional rather than final. Future case law may affect the recommendations. Modifications to the Leaflet may be suggested after its wider use, and comments or suggestions are welcome from readers.

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References list

1. Smith AM. Obtaining consent for examination and treatment. *BMJ* 2001;322(7290):810-1.
2. Reference guide to consent for examination or treatment. Department of Health. <http://www.doh.gov.uk/consent/refguide.htm> (accessed 10 September 2001).
3. 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.
4. 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.
5. Seeking patients' consent: the ethical considerations. General Medical Council, London (accessed September 2001).
6. Peuker ET, Grönemeyer DHW. Risk information and informed consent in acupuncture – a proposal from Germany. *Acupunct Med* 2001;19(2):137-41.
7. Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] AC 871.
8. Vincent C. The safety of acupuncture. *BMJ* 2001; 323(7311):467-8.

Patient Information and Consent Form

Please read this information carefully, and ask your practitioner if there is anything that you do not understand.

What is acupuncture?

Acupuncture is a form of therapy in which fine needles are inserted into specific points on the body.

Is acupuncture safe?

Acupuncture is generally very safe. Serious side effects are very rare – less than one per 10,000 treatments.

Does acupuncture have side effects?

You need to be aware that:

drowsiness occurs after treatment in a small number of patients, and, if affected, you are advised not to drive;

minor bleeding or bruising occurs after acupuncture in about 3% of treatments;

pain during treatment occurs in about 1% of treatments;

symptoms can get worse after treatment (less than 3% of patients). You should tell your acupuncturist about this, but it is usually a good sign;

fainting can occur in certain patients, particularly at the first treatment.

In addition, if there are particular risks that apply in your case, your practitioner will discuss these with you.

Is there anything your practitioner needs to know?

Apart from the usual medical details, it is important that you let your practitioner know:

if you have ever experienced a fit, faint or funny turn;

if you have a pacemaker or any other electrical implants;

if you have a bleeding disorder;

if you are taking anti-coagulants or any other medication;

if you have damaged heart valves or have any other particular risk of infection.

Single-use, sterile, disposable needles are used in the clinic.

Statement of Consent

I confirm that I have read and understood the above information, and I consent to having acupuncture treatment. I understand that I can refuse treatment at any time.

Signature

Print name in full

Date

Patient Information Leaflet

Please read this information carefully, and ask your practitioner if there is anything that you do not understand.

What is acupuncture?

Acupuncture is a form of therapy in which fine needles are inserted into specific points on the body. Some practitioners also use a smouldering herb called 'moxa' to warm these points.

Is acupuncture safe?

Acupuncture is generally very safe. Serious side effects are very rare – less than one per 10,000 treatments.

Does acupuncture have side effects?

You need to be aware that:

drowsiness occurs after treatment in a small number of patients, and, if affected, you are advised not to drive;

minor bleeding or bruising occurs after acupuncture in about 3% of treatments;

pain during treatment occurs in about 1% of treatments;

existing symptoms can get worse after treatment (less than 3% of patients). You should tell your acupuncturist about this, but it is usually a good sign;

fainting can occur in certain patients, particularly at the first treatment.

In addition, if there are particular risks that apply in your case, your practitioner will discuss these with you.

Is there anything your practitioner needs to know?

Apart from the usual medical details, it is important that you let your practitioner know:

if you have ever experienced a fit, faint or funny turn;

if you have a pacemaker or any other electrical implants;

if you have a bleeding disorder;

if you are taking anti-coagulants or any other medication;

if you have damaged heart valves or have any other particular risk of infection.

Single-use, sterile, disposable needles are used in the clinic.

Research Reviews

This section is designed to give a synopsis of some of the latest research published in medline listed journals over the last year or so. It will concentrate on controlled trials and systematic reviews, but will also include other papers that may be of interest to the readership. Some papers will be reviewed in more detail than others. If summaries and comments are based on an abstract only, this will be indicated. The main reviewer in this section is Mike Cummings, London. Other reviewers are indicated after the relevant review.

SR

A systematic review of adverse events following acupuncture from the Japanese literature

Yamashita H, Tsukayama H, White AR, Tanno Y, Sugishita C, Ernst E. Systematic review of adverse events following acupuncture: the Japanese literature. *Complement Ther Med* 2001;9(2):98-104.

Summary

Many Japanese cases of adverse events after acupuncture are not listed in medical databases such as Medline. Therefore, they are not easily accessible to researchers outside Japan. This paper was written to complement existing reviews of adverse events after acupuncture in the West. A literature search was performed using 'Igakku Chuo Zasshi (Japana Centra Revuo Medicina) covering the period of 1987-1999. Case reports of adverse events judged to be related to acupuncture treatment were included. Experimental studies, surveys, and news articles were excluded. Two independent reviewers extracted data from included papers in a pre-defined and structured way, and assessed likelihood of causality in each individual case. Eighty-nine articles reporting 124 cases were located. The most frequent adverse events were: pneumothorax (25 cases), spinal cord injury (18 cases), acute hepatitis B (11 cases), and localized argyria (10 cases). The latter refers to a deep duskiness of the skin, probably resulting from deposition of silver salts. There were two fatalities from infections. Forty-eight events were caused by

needle breakage including 26 cases of intentionally embedded needles and 16 cases of accidental breakage. There were also 10 cases of injury from self-treatment. The authors concluded: 'Although it has already been demonstrated that severe adverse events seem to be uncommon in standard practice, many serious cases of negligence have been found in the present review, suggesting that training systems for acupuncturists (including medical doctors) should be improved and that unsupervised self-treatment should be discouraged.'

Comment

Nineteen of the 89 articles included in the review were also listed in Pubmed – a database, derived from Medline, which is searchable via the internet. Seventy were effectively hidden from the western literature. The authors note that none of the adverse events were reported by acupuncturists, and that the reports were not found in literature that would be read by most acupuncturists in Japan. Clearly links must be established so that adverse events can inform acupuncture education and clinical practice.

Clinical Papers

Autonomic dysreflexia may be a risk in some patients with spinal cord injuries undergoing acupuncture (n=15)

Averill A, Cotter AC, Nayak S, Matheis RJ, Shiflett SC. Blood pressure response to acupuncture in a population at risk for autonomic dysreflexia. *Arch Phys Med Rehabil* 2000;81(11):1494-7.

Summary

This study was designed to determine whether acupuncture can lead to autonomic dysreflexia (AD) when used to treat chronic pain in individuals with spinal cord injury (SCI). Fifteen patients with post-SCI chronic pain who were at risk for AD (ie, SCI at or above T8) were given half-hour acupuncture treatment sessions twice a week for 7.5 weeks, for a total of 15 treatments. Acupuncture needles were inserted both above and below the patient's spinal lesion level. Blood pressure (BP) was measured before and after acupuncture treatments. On average, systolic BP (SBP) and diastolic BP (DBP) remained stable across all 15 treatment sessions. None of the participants experienced any symptoms of AD. However, examination of individuals' BP readings indicated acute elevations (20mmHg or higher) in SBP for three of the 15 participants. The authors concluded that although none of the 15 participants who were at risk for developing AD developed symptoms consistent with this diagnosis, three displayed an acute elevation in SBP, suggesting a pattern of imminent AD. Comorbid hypertension appeared to contribute to the elevation in 1 patient. The authors advise that patients with SCI or hypertension are carefully monitored during acupuncture treatment.

Comment

The introduction to this paper gives some background on autonomic dysreflexia:

'The reported incidence of autonomic dysreflexia (AD) among individuals with spinal cord injuries (SCIs) ranges from 48% to 85%. Clinically AD presents as hypertension, and may be associated with bradycardia, severe headache, perspiration and flushing above the level of the lesion, anxiety, nasal congestion, cardiac arrhythmias, visual changes, and goose bumps over or below the lesion. Usually these signs and symptoms are precipitated by noxious stimuli below the level of the spinal cord lesion in persons with injuries at or below the mid-thoracic (T6-T8) level. An elevation in blood pressure (BP) of 20 to 40mmHg above the baseline value may be considered to be a sign of AD. Acute hypertension can be potentially

dangerous and have grave consequences including stroke and seizure, and therefore, must be monitored closely and treated as a medical emergency. The most common causes of AD are bladder distension and bowel distension. It may, however, be caused by any painful or irritating stimuli below the level of the lesion, including contact with sharp objects...'

Autonomic dysreflexia is clearly worth consideration when treating SCI patients with acupuncture. The authors of this paper were clearly erring on the side of caution, which is understandable. It should be noted, however, excluding the patient with known hypertension, there were only two occasions in which SBP rose by 20mmHg out of 210 acupuncture sessions (0.95%). Including the patient with hypertension, the figures were seven occasions in 225 sessions (3.1%). Whilst a rise in BP may be a sign of impending AD, we do not know how often such a rise in BP occurs in normal subjects during acupuncture treatment.

Adverse reactions related to acupuncture in Japan I (n=65,482)

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. [Abstract]

Summary

Many of the reported adverse effects of acupuncture are serious or severe such as pneumothorax, infection, spinal cord injury, or cardiac injury. However, reviewing published case reports does not provide enough information to assess the safety of acupuncture and moxibustion. In order to investigate adverse events of acupuncture, the authors reviewed all the relevant cases reported by the therapists at their clinic. Over a 6-year period, in the national Tsukuba College of Technology Clinic in Japan, all the acupuncture and moxibustion therapists were required to report the cases of adverse events immediately upon recognition. A total of 84 therapists participated in

the treatments. The total number of treatments was 65,482. Ninety-four (0.14%) adverse events were reported. There were fourteen categories: failure to remove needles (27 cases), ecchymosis or hematoma without pain (9 cases), ecchymosis or hematoma accompanied by pain (8 cases), burn injury (7 cases), discomfort (7 cases), dizziness (6 cases), nausea or vomiting (6 cases), pain in the punctured region (6 cases), minor hemorrhage (4 cases), aggravation of complaint (4 cases), malaise (3 cases), suspected contact dermatitis (3 cases), fever (3 cases) and numbness in the upper extremities (1 case). No serious or severe cases were reported. The results indicate that serious or severe adverse events are rare in standard practice. The authors suggest that most severe or serious cases of adverse events caused by acupuncture reported in journals are actually cases of negligence. They recommend that such cases be used to inform medical education.

Comment

This survey covered almost the same total number of treatments as the two surveys reported in this issue combined. The frequency of events reported, however, is considerably lower in this paper. The Japanese style of acupuncture tends to involve rather superficial needling, but this is not the main reason for the difference. This paper relied on the therapist or patient considering an event or reaction to be significant enough to report. All serious adverse events are likely to have been picked up by this system, so the results are useful in assessing the safety of acupuncture in this setting, but the minor reactions following treatment could easily have been underestimated. Thus the authors went on to perform a more meticulous review of adverse reactions in a smaller sample (see below).

Adverse reactions related to acupuncture in Japan II (n=1441)

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.

Summary

This survey was designed to determine the type, severity, and incidence of acupuncture adverse reactions observed in standard practice. It was based on observation and interviews by the therapists at Tsukuba College of Technology Clinic in Japan. The survey included all patients who underwent acupuncture treatment during a period of four months from April to July 1998. The type, severity, and incidence of acupuncture adverse reactions were recorded. A total of 391 patients were treated in 1,441 sessions, involving a total of 30,338 needle insertions. The incidence of recorded systemic reactions in individual patients was: tiredness (8.2%); drowsiness (2.8%); aggravation of preexisting symptoms (2.8%); itching in the punctured regions (1.0%); dizziness or vertigo (0.8%); feeling of faintness or nausea during treatment (0.8%); headache (0.5%); and chest pain (0.3%). The incidence of recorded local reactions, expressed as a percentage of needle insertions, was: minor bleeding on withdrawal of the needle (2.6%); pain on insertion of the needle (0.7%); petechia or ecchymosis (0.3%); pain or ache in the punctured region after the treatment (0.1%); subcutaneous haematoma (0.1%); and pain or discomfort in the punctured region during the needle retention (0.03%). The authors concluded that although some adverse reactions associated with acupuncture were common even in standard practice, they were transient and mild compared to cases such as pneumothorax, cardiac injury, infection, or spinal lesions reported in other studies.

Comment

This paper completes a trilogy by Yamashita et al in this section of reviews on safety related papers. It constitutes a smaller, more meticulous survey of the reactions following acupuncture. In surveying considerably fewer treatment sessions, the reliability of these estimates of the frequency of various adverse reactions is necessarily somewhat lower than the two surveys reported in this issue. The differences in rates of events, however, may reflect other factors. One of the key determinants of the rate of reported events after a treatment is

whether or not the patient is actually asked. In this study patients were specifically asked to report symptoms, whereas in the SAFA study events were only recorded if recognised by practitioners or spontaneously reported by patients. Other potential differences derive from the nature of techniques in common practice in Japan compared with the UK, and in the cultural differences between the populations.

Experimental Studies (animals)

Acupuncture at LI4 suppresses oxytocin induced uterine contractions in pregnant rats (n=6)

Pak SC, Na CS, Kim JS, Chae WS, Kamiya S, Wakatsuki D *et al.* The effect of acupuncture on uterine contraction induced by oxytocin. *Am J Chin Med* 2000;28(1):35-40.

Summary

Preterm labor (PTL) is one of the main causes of fetal mortality and morbidity in obstetrical medicine. Current methods of treatment are not very effective and often have significant side effects. For this reason new methods of preventing PTL are currently being sought. In western medicine the newest development is oxytocin antagonists. In oriental medicine acupuncture and moxibustion are being utilized for the purpose of stopping PTL. The goals of this study were to determine if acupuncture in pregnant rats can suppress oxytocin induced uterine contractions and to compare these results with those inhibited by an oxytocin antagonist. Uterine contractions were induced by continuous infusion of exogenous oxytocin. The first fetus in one uterine horn near the ovarian end was removed and a distilled water-filled catheter was inserted into that vacated amniotic sac to measure uterine contractions as intrauterine pressure changes. Two acupoints - LI4 & SP6 - were selected for acupuncture and CV4 was used for moxibustion. The oxytocin-induced uterine contractions were

significantly suppressed by acupuncture at LI4 ($p < 0.05$), but not at SP6. Stimulation of CV4 by moxibustion had no significant tocolytic effect ($p > 0.05$). The administration of an oxytocin antagonist eliminated all the uterine contractions induced by oxytocin. The application of acupuncture to re-stimulate the activity that was suppressed by the oxytocin antagonist was unsuccessful, but prostaglandins did generate uterine contractions. The authors concluded that acupuncture at LI4 was effective in suppressing uterine contractions induced by oxytocin in pregnant rats. If acupuncture is similarly effective in counteracting the effects of oxytocin in women, then this may be an alternative medical treatment for women in preterm labour.

Comment

This review has been included because of the reluctance of doctors to use acupuncture in pregnancy. This reluctance stems not from the risk of adverse events per se, but more from the worry that the practitioner will be blamed for some spontaneous event occurring after acupuncture treatment. Indeed, it is possible that acupuncture could prove to be one of the safer interventions during pregnancy, should someone be bold enough to test the hypothesis.

This study suggests that needling the forelimb of a pregnant rat has a more significant effect on oxytocin induced uterine contractions than needling the hind limb. One hypothesis is that strong somatic stimulation to the forelimb mimics a survival situation involving fighting, and thus greater endorphin release and suppression visceral activity, whereas hind limb stimulation may simply reflect locomotion. It is rather contentious to suppose that the point LI4 has the same significance in a small furry quadruped as it does in man – an animal with highly sophisticated motor and sensory functions in the hand; however, premature labour seems a worthy area to test acupuncture in view of the fact that current orthodox treatments are rather less than satisfactory.

Despite the fact that acupuncture was not able to stimulate uterine contractions in this trial, it

would be a rather optimistic to expect that this result in a small group of pregnant rats alone would sway the opinion of any judge; so acupuncturist must continue to be cautious of needling pregnant women for the time being.

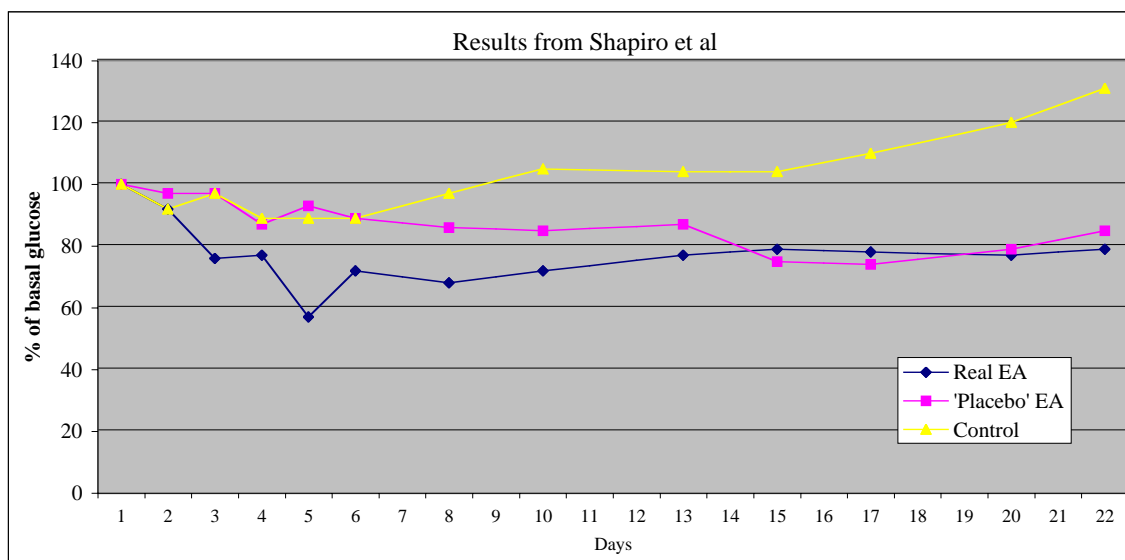
Electroacupuncture has hypoglycaemic effect in rats (n=29)

Shapira MY, Appelbaum EY, Hirshberg B, Mizrahi Y, Bar-On H, Ziv E. A sustained, non-insulin related, hypoglycaemic effect of electroacupuncture in diabetic *Psammomys obesus*. *Diabetologia* 2000;43(6):809-13.

Summary

This experiment was designed to investigate the effect of electroacupuncture (EA) in *Psammomys obesus* ('sand rat'), a model of insulin resistance and non-insulin-dependent diabetes mellitus. Twenty-nine diabetic *Psammomys* were randomly assigned to three groups: abdominal EA (real, n=11), EA on the back EA (placebo, n=9) and control (anaesthesia, n=9). EA was carried out on days one, three and five of the experiment. It was performed under anaesthetic, and the stimulation was applied at 80mA and 15Hz for a period of 30 minutes. During the first week of the experiment, blood glucose was tested three times on treatment

days and once on the following days. Over the next two weeks, blood glucose was tested every other day. Animals were weighed at the same time of blood sampling. After three weeks, at the end of the experiment, blood was drawn for measurement of insulin, fructosamine, cholesterol and triglycerides. At day five (end of intervention), blood glucose (as per cent of primary concentrations, means +/- SE) was 57 +/- 10, 93 +/- 13 and 89 +/- 11 for the real, placebo and control groups respectively (p=0.02). At day 8, blood glucose 68 +/- 14, 86 +/- 16 and 97 +/- 9 for the real, placebo and control groups respectively (p=0.04). At day 22, blood glucose was 79 +/- 11, 85 +/- 15 and 131 +/- 2 for the real, placebo and control groups (p=0.04). Comparison of the decline in blood glucose, throughout the three weeks, between the real and placebo groups by ANOVA was highly significant (p<0.0001), the difference between the placebo and control groups at the same time was not significant (p>0.05). Animal weight gain, serum insulin, fructosamine, cholesterol and triglycerides were not significantly different between real and placebo groups. The authors concluded that EA at special abdominal acupoints induces a sustained hypoglycaemic effect in diabetic *Psammomys* compared with EA at non-specific points, without weight loss. No



hypoinsulinaemic effect was shown in the real and placebo groups.

Comment

Why has this experimental study been reviewed in an issue devoted to safety? Well, it is often said that acupuncture may reduce the insulin requirements in diabetic patients, and therefore we should warn such patients to monitor their blood glucose more closely whilst undergoing acupuncture treatment.

This study is somewhat removed from the clinical setting, however, it does appear to support the empirical contention that there is a hypoglycaemic effect following acupuncture. This reviewer is not convinced from the data presented, however, that there is much difference between EA applied to the abdomen (CV12 & CV4) and EA applied to paravertebral muscle. The figure above is a representation of the data presented in the paper. The blood glucose of the abdominal EA group (REA) does appear to decrease significantly during the treatment phase, however, the back EA group (PEA) catches up after a week, and the control group gradually rises throughout. It is not clear from the paper, though it is implied, that these rats would be expected to become hyperglycaemic over time whilst on a laboratory diet.

What can we conclude from this paper? There may be a hypoglycaemic effect from EA, and this effect may be greater from stimulating the abdomen, however, this paper does not support the specificity of the abdominal acupuncture points used.

Reports of Adverse Events & Related Papers

Allergy to nickel causes contact dermatitis following acupuncture (n=1)

Morimoto M, Kawata K, Tsuchiya N, Murakami H, Kura M, Koga Y. [A case of acupuncture needle dermatitis]. *Masui* 2000;49(8):887-9.

Summary

A 65-year-old female visited the author's clinic with a painful red vesicular dermatitis of the forehead and around the left eye. She had received acupuncture for headache and shoulder stiffness 6 days previously. A patch test with nickel sulfate gave positive results. She was treated with a greater occipital nerve block and trigger point injection. This treatment relieved her pain, and the author's reached the diagnosis of greater occipital trigeminal syndrome with contact dermatitis from the acupuncture needles.

Comment

There have been several reports of contact dermatitis following acupuncture. Reactions have occurred to zinc and chromium as well as nickel. This paper is written in Japanese with an abstract in English, so there is limited information accessible to the reviewer. It is difficult to determine the strength of the association between the acupuncture treatment and the dermatitis. The incidence of this type of reaction following acupuncture is extremely low, but what should we do in the case of a patient presenting for treatment who is known to have a metal allergy? This reviewer would suggest treatment that involved brief needling with silicone-coated needles as one option, provided, of course, that acupuncture was indicated in the first place.

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Adverse Events Associated with Acupuncture Reported in 2000

Sir,

Although British doctors and physiotherapists reported no serious adverse events in over 30,000 consultations,¹ reports of such events still appear in the world literature. In continuation from previous projects,^{2,3} we again searched Medline, Embase and our own records for new data on adverse events associated with acupuncture that were reported in the year 2000.

Seven case reports are listed in table 1, the first three of which were life-threatening.⁴⁻¹⁰ However, all patients made a complete recovery. The other untoward event reported as a case history was the discovery of a needle in a patient's scalp as she was being prepared for emergency Caesarean section because of foetal bradycardia.¹¹

Norwegian researchers sent questionnaires to a random sample of the Norwegian general population.¹² Of the 653 respondents, 7% claimed to have experienced adverse effects of acupuncture. The most common effects reported were dizziness, fatigue and pain from the needles. No serious adverse effects were reported. A survey of 1100 Australian

providers of Traditional Chinese Medicine asked them to recall any adverse events of acupuncture in their practice.¹³ A total of 3222 events were recalled including 64 cases of pneumothorax and 80 convulsions. No fatalities were on record.

Acupuncture needles are a potential source of blood-borne infection, except for single-use disposable needles. Korean epidemiologists studied the prevalence of hepatitis C virus infection in a rural population (n=1033) with a high incidence of liver cancer.¹⁴ Using a multivariate analysis, they noted that the strongest risk factor associated with hepatitis was the use of acupuncture (odds ratio = 2.2, 95% CI 1.0 – 4.7). In a health survey of 303 volunteers in rural France, however, acupuncture was not associated with higher risk for serum hepatitis A, B or C markers, even though it was used by 17% of respondents.¹⁵ In the US, a case-control study involving 2316 blood donors identified as hepatitis C positive concluded that acupuncture was not a risk factor for hepatitis C.¹⁶ The UK cannot be regarded as totally safe from risk of hepatitis associated with acupuncture: an acupuncturist using a different technique (re-injecting the patient's own blood, diluted with saline, into acupuncture points) was apparently responsible for causing at least 30 cases of hepatitis B, some of which became chronic.¹⁷ Contaminated saline in a repeatedly used bottle was the likely source.

Finally, a technical review of three electroacupuncture stimulators found that their performance did not meet the manufacturer's claims, which was particularly serious in one aspect: the net current passed at high frequencies might cause tissue damage, electrolysis and degradation of the needle.¹⁸ The authors concluded that outputs of electroacupuncture stimulators should be calibrated and practitioners should be trained in their use. Taking a world-wide perspective, it is clear that acupuncture training and practice has some way to go before acupuncture as a therapy can be declared to be as safe as possible.

Table 1 Summary of seven case reports of adverse events associated with acupuncture in 2000

First author (Country)	Adverse event	How causality established	Risk factor identified	Causality
Choo ⁴ (USA)	Intracranial haemorrhage	CT scan	Needling neck	Probable
Kirchgatterer ⁵ (Austria)	Cardiac tamponade	Immediate event	Needling sternum	Definite
Origuchi ⁶ (Japan)	Infectious aortic aneurysm	Surgery	Indwelling treatment	Definite
McCartney ⁷ (Britain)	Bilateral hand swelling	Timing of event	None	Probable
Yanigahara ⁸ (Japan)	Silicone granuloma	Electron microscopy	Idiosyncrasy	Definite*
Castro-Duran ⁹ (Spain)	Pyoderma gangrenosum	History	Ulcerative colitis	Probable
Morimoto ¹⁰ (Japan)	Contact dermatitis	History, location	Nickel allergy	Definite

* Also occurred with venepuncture and surgical needles

Reference List

- 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.
- Ernst E, White AR. Indwelling needles carry greater risks than acupuncture techniques. *BMJ* 1999;318(7182):536.
- Ernst E, White AR. Acupuncture may be associated with serious adverse events. *BMJ* 2000;320:513-4.
- Choo DC, Yue G. Acute intracranial hemorrhage caused by acupuncture. *Headache* 2000;40(5):397-8.
- Kirchgatterer A, Schwarz D, Hoeller E, Punzengruber C, Hartl P, Eber B. Cardiac tamponade following acupuncture. *Chest* 2000;117:1510-1.
- Origuchi N, Komiyama T, Ohyama K, Wakabayashi T, Shigematsu H. Infectious aneurysm formation after depot acupuncture. *Eur J Vasc Endovasc Surg* 2000;20(2):211-3.
- McCartney CJL, Herriot R, Chambers WA. Bilateral hand oedema related to acupuncture. *Pain* 2000;84:429-30.
- Yanagihara M, Fujii T, Wakamatu N, Ishizaki H, Takehara T, Nawate K. Silicone granuloma on the entry points of acupuncture, venepuncture and surgical needles. *J Cutan Pathol* 2000;27(6):301-5.
- Castro-Duran J, Martin-Armada M, Jimenez-Alonso J. Pyoderma gangrenosum induced by acupuncture in a patient with ulcerative colitis. *Arch Intern Med* 2000;160:2394.
- Morimoto M, Kawata K, Tsuchiya N, Murakami H, Kura M, Koga Y. [A case of acupuncture needle dermatitis]. *Masui* 2000;49(8):887-9.
- Krosnar S, Clark V. Crashed and nearly burned ... during a LSCS! [letter]. *Anaesthesia* 2000;55(9):936.
- Norheim AJ, Fonnebo V. A survey of acupuncture patients: results from a questionnaire among a random sample in the general population in Norway. *Complement Ther Med* 2000;8(3):187-92.
- Bensoussan A, Myers SP, Carlton AL. Risks associated with the practice of traditional Chinese medicine: an Australian study. *Arch Fam Med* 2000;9:1071-8.
- Shin HR, Kim JY, Ohno T, Cao K, Mizokami M, Risch H *et al.* Prevalence and risk factors of hepatitis C virus infection among Koreans in rural are of Korea. *Hepatology Research* 2000;17:185-96.
- Nalpas B, Zylberberg H, Dubois F, Presles MA, Gillant JC, Lienard M *et al.* [Prevalence of infection by hepatitis viruses in a rural area. Analysis according to risk factors and alcohol consumption]. *Gastroenterol Clin Biol*. 2000;24(5):536-40.
- Murphy EL, Bryzman SM, Glynn SA, Ameti DI, Thomson RA, Williams AE *et al.* Risk factors for hepatitis C virus infection in United States blood donors. NHLBI Retrovirus Epidemiology Donor Study (REDS). *Hepatology* 2000;31(3):756-62.
- Webster GJ, Hallett R, Whalley SA, Meltzer M, Balogun K, Brown D *et al.* Molecular epidemiology of a large outbreak of hepatitis B linked to autohaemotherapy. *Lancet* 2000;356(9227):379-84.
- Lytle CD, Thomas BM, Gordon EA, Krauthamer V. Electrostimulators for acupuncture: safety issues. *J Altern Complement Med* 2000;6(1):37-44.

Risk information and informed consent in acupuncture – A proposal from Germany

Sir,

Informed consent has become an important part of medical practice. It requires the communication of information about possible adverse effects of treatment.

Although serious adverse effects of acupuncture seem to be very rare,¹ case reports of traumatic complications and indirectly caused side-effects appear regularly in scientific publications.²

Acupuncturists have expressed concern, however, that increased provision of risk information may make patients unduly anxious and change their decisions about treatment.³

It has been our experience that provision of detailed information about possible adverse consequences of treatment can improve patients' understanding and satisfaction without inducing increased anxiety. Meanwhile this has been proven by several studies.⁴

In our department, patients are enlightened orally and in written form about the risks and possible benefits of the acupuncture therapy. They fill out and sign a form with questions about their medical history and individual risk factors.

In the attached appendix we present our risk information and informed consent forms which we developed especially for acupuncture therapy. Readers are strongly encouraged to discuss this proposal, to shorten it where possible, and to refine it where necessary.

Reference list

- Ernst E, White AR. Prospective studies of the safety of acupuncture: a systematic review. *Am J Med* 2001;110(6):481-5.
- Peuker ET, White A, Ernst E, Pera F, Filler TJ. Traumatic complications of acupuncture. Therapists need to know human anatomy. *Arch Fam Med* 1999; 8(6):553-8.
- "The safe practice of acupuncture conference" Discussion. London, 2001, June 19th.
- Garrud P, Wood M, Stainsby L. Impact of risk information in a patient education leaflet. *Patient Educ Couns* 2001; 43(3):303-6.

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Information consultation/Consent “What you should know...”

Acupuncture

Patient name and address

Professorial chair for radiology and microtherapy
University of Witten/Herdecke
Prof. Dietrich H.W. Grönemeyer, M.D.
The Grönemeyer-Institute of Microtherapy
Department of Traditional Medicine
Director: Elmar T. Peuker, M.D.

Please read and answer carefully before the information consultation.

Dear Patient/Parents:

Acupuncture is a very old therapy technique that can be quite beneficial in the treatment of many different illnesses.

In this procedure needles are inserted at individually determined points of the body, where they are left for a while. During this period you should attempt to relax.

We use exclusively high-quality, sterile disposable articles.

To optimize the therapeutic effect, it may be necessary to introduce additional measures, such as e.g. electrical stimulation of the needles or moxibustion, in which the Chinese herb mugwort (*Artemisia vulgaris*) is ignited.

Before the treatment starts, our physicians will discuss your illness with you in a detailed consultation and conduct a comprehensive physical examination. If we are of the opinion that additional diagnostic steps are necessary, we shall discuss the appropriate recommendations with you.

We consider it important that you bring all your available examination documents with you to your appointment, so that together we can determine the best possible comprehensive picture of your medical history.

Should you be concerned about side effects?

Acupuncture is a procedure with few side effects; however, as with any other effective therapy, side effects may occur under unfavorable conditions, although severe complications are highly unlikely. However, we consider it important that you be informed about this topic. By carefully filling out the accompanying questionnaire, you help us further reduce the already low risk.

The following list covers the conceivable side effects with comments on their evaluation:

- After acupuncture almost all patients experience relaxation, which is usually perceived as beneficial. Please bear in mind that the ability to drive an automobile may be impaired, so you should use public transportation or allow someone else, for example a relative, to drive.
- Some people react to needle pricks with impaired circulation, up to and including circulatory collapse. Persistent injury has so far not been reported. To minimize the risk, if at all possible we shall perform the therapy with the patient in the lying position.
- Very small bruises at puncture sites occur frequently, because damage to the cutaneous vessels is unavoidable. Further treatment is as a rule not required. If you take blood-thinning medication, please indicate this on the information form.
- In principle, any invasive procedure can produce a localized or spreading infection. We minimize this risk by using sterile disposable needles and by disinfecting especially infection-prone areas, such as e.g. the outer ear. For this reason, please indicate on the questionnaire if you take medication that impairs the immune system or suffer from diabetes or other chronic disease. After the treatment, if you suspect an infection at a puncture site, please come to our office immediately or seek medical attention elsewhere.
- Small nerves may rarely be damaged, which can result in transient, mild paraesthesia. Lesions on larger nerves and vessels are rare, but in certain cases might require further diagnostics and therapy.

- Although damage to internal organs can be almost completely ruled out with our cautious needle technique, it has been reported in medical literature. In such a case, we would naturally respond immediately with adequate measures.

- During moxibustion, burns or allergic reactions to mugwort can occur under unfavorable conditions.

You can help us reduce this risk by indicating on the questionnaire whether you have allergies and/or an asthmatic condition.

- Although we use exclusively high-quality, tested acupuncture needles, in rare cases they can break off. In such a case steps would have to be taken to remove the rest of the needle.

During the consultation with your therapist, please ask about anything you wish to know.

Your therapy team

Consent

Please do not fill out and sign until after the information consultation.

I have received and carefully read the information form. I have understood the questions and answered them to the best of my knowledge.

Acupuncture therapy and its possible side effects were thoroughly explained to me. My questions were answered completely and intelligibly.

Notes:

After careful consideration I agree to the acupuncture treatment.

I do not agree to the acupuncture treatment. I have been informed that my decision could impede the therapy of my illness.

Bochum,

Date:

(Therapist's signature)

(Patient's signature)

Questionnaire on the information consultation “What we should know...”

Acupuncture

Patient name and address

Professorial chair for radiology and microtherapy
University of Witten/Herdecke
Prof. Dietrich H.W. Grönemeyer, M.D.
Institute of Microtherapy
Department of Traditional Medicine
Director: Elmar T. Peuker, M.D.

Please read this questionnaire before the information consultation and fill it out as much as possible. Please ask if anything is not clear.

Thank you very much – Your therapy team

Medications

- Are you currently taking medications that influence blood clotting (e.g. aspirin, warfarin or similar drugs)?

yes no

If yes, which medication(s) and in what dosage?

- Are you currently taking medication that influences the immune system (e.g. steroids or cancer treatment drugs)

yes no

If yes, which medication(s) and in what dosage?

- Are you currently taking antibiotics?

yes no

If yes, which antibiotics and in what dosage?

- Are you taking any other medication?

yes no

If yes, which medication(s) and in what dosage?

Diseases

- Do you suffer from impaired wound healing or a blood coagulation disorder?

yes no

If yes, which disorder and with which therapy are you being treated?

- Do you now or have you ever had a malignant disease?

yes no

If yes, which disease, since when and with which therapy are you being treated/were treated?

- Do you now or have you ever had heart disease (e.g. endocarditis or myocarditis,

perforated cardiac septum, valvular disease, myocardial infarction)?

yes no

If yes, which disease, since when and with which therapy are you being treated/were treated?

• Do you suffer from diabetes mellitus?

yes no

If yes, since when and with which therapy are you being treated?

• Have you ever had an organ or tissue transplantation?

yes no

If yes, what and when?

• Do you suffer from a chronic kidney disease?

yes no

If yes, from which disease, since when and with which therapy are you being treated?

• Do you suffer from a rheumatic disease?

yes no

If yes, from which disease, since when and with which therapy are you being treated?

• Do you have any known allergies (including neurodermatitis, hay fever)?

yes no

If yes, which allergies and with which therapy are you being treated?

• Do you suffer from a chronic lung disease (e.g. asthma, chronic obstructive bronchitis, emphysema)?

yes no

If yes, from which disease, since when and with which therapy are you being treated?

• Do you or have you ever suffered from a psychological disorder?

yes no

If yes, which disorder, since when and with which therapy are you being treated/were treated?

• Do you or have you ever suffered from a convulsive disorder (epilepsy, convulsions)?

yes no

If yes, which disorder, since when and with which therapy are you being treated/were treated?

• Do you have any chronic infectious diseases (e.g. hepatitis or HIV)?

yes no

If yes, which disease(s)?

Thank you for your cooperation.

Reviews

Acupuncture: Techniques for Successful Point Selection

Royston Low

Paperback, Pages: 118, Price: £15.99
Butterworth Heinemann, Oxford 2001
ISBN 0 7506 4852 X

This slim volume gives a very concise yet comprehensive account of the author's 'energetic' views on acupuncture by considering three fundamental approaches - the five elements, antique (or command) points, and the eight approaches (or principles). Low then elaborates on his 12 rules of acupuncture by detailing points such as Ah Shi, local and distal, key, special, Shu and Mu, and formulae. The book is very traditional Chinese medicine (TCM) orientated, despite claims to combine western and traditional Chinese approaches. In describing Ah Shi points, Low puts down "Scientific brethren" saying "if

you stick the needle in where it hurts you often get amazing results!" The western technique of acupuncture is not considered apart from scant reference to trigger points.

Needle techniques are aimed at restoring energy, by removing the blockage or transferring or equalising excess. The angle of insertion, needle depth, rotation, and degree of 'waggle' are well described as needle manipulations. Finally, specific techniques such as moxa, the Plum-Blossom needle, cupping, finding the point, and formulating treatment, are summarised in the remaining chapters.

The book is aimed at traditional practitioners who have a sound knowledge of basic TCM and wish to improve technique and treatment success. The book does this admirably, and represents good value. Western medical acupuncturists will be disappointed.

Colin Lewis

Auricular Acupuncture Bibliography (Classifications and Abstracts)

André Lentz

Paperback, Pages: 352, Price: FFr 150
Available from the author, 2000
auriculo@ifrance.com

Auricular acupuncture is widely used. However, the details of its development and of any research that supports its use are mostly tucked away inaccessibly in obscure publications. This book, despite some shortcomings, makes it easier at least to know what has been published.

Paul Nogier first developed auricular acupuncture in the 1950s, and over the years, until his death in 1996, embellished and elaborated it into sprawling systems of auriculotherapy and auriculomedicine. The two lynchpins of these are

the map of auricular points, supposedly corresponding to different anatomical and physiological systems, and the VAS ('vascular autonomic signal') or ACR ('auricular cardiac reflex'), a change in the pulse in response to even very subtle stimuli to the ear, or elsewhere on the body. A much simpler, more pragmatic approach, with its own vast literature, was developed in China over the same period, although interestingly the Chinese did not, by and large, adopt the VAS. In Russia, important discoveries have been made on the neurophysiology of auricular stimulation.

André Lentz has taken on the formidable task of organising this literature into one bibliography, in three parts. The first is a listing of books, articles and conference abstracts, by author (p. 112), the second is the same material, generally with full references, organised by themes (p. 129), and the third is a collection of some of the

available abstracts from the references already listed (69 pp). Abstracts are not necessarily in English, though some are, in addition to their original language. Full keyword and author indexes complete the book.

Clearly, much of the Chinese literature has not found its way into this bibliography. Given a more complete listing of Chinese sources, I would be intrigued to see if the French retained their pre-eminence in terms of numbers of studies published. Somehow, I doubt it. On the other hand, there appears to be a considerable amount of Spanish language literature on auricular acupuncture, and a relative paucity of Japanese research in the area. Only 3 articles by Scandinavian authors are listed, which is surprising, given their dedication to acupuncture research in general.

A grave concern I have is the paucity of good quality research validating some of the basic premises on which Nogier and his followers have constructed the elaborate edifice of auriculomedicine. Oleson's early work on auricular point detection stands out, as do the more recent fastidious studies by Arthur Margolin's group at Yale University, but there is little good research validating the VAS/ACR which, like the Chinese pulse, depends a great deal on the sensitivity and clinical orientation of the pulse taker. However, it seems that Ackerman (and to some extent Navach) have done some interesting work in this area.

This book was compiled hurriedly, its appearance timed to coincide with a 2000 conference arranged by the Group Lyonnais d' Etudes Medicales (GLEM). As a result, it is far from complete, and the 40 categories chosen to organise the material in the second part are somewhat haphazard. However, its author sees the book as a collaborative and ongoing project, and urges readers to assist in its improvement (a CD-Rom and website presence were originally also planned). Symptomatic of the haste with which it was prepared are numerous duplicated entries, incomplete reference details, inconsistencies of format, and occasional errors in cross-referencing between the different sections. Authors' addresses are sometimes given, but usually not.

All in all, though, these faults are minor ones. For anyone who wishes to know about the published literature on auricular acupuncture and its variants, this book will now be an essential resource. On the basis of André Lentz's considerable labours, an international commission on auricular bibliography has been established, headed by Terry Oleson (Lentz himself is no longer involved in the project). I hope that in future editions the numbers of abstracts will be greatly expanded, and also a link established to a central organisation (GLEM?) where copies of the relevant papers can be easily obtained. In this way, the auricular literature will become much more readily accessible to all of us.

David Mayor

Myofascial Pain and Fibromyalgia Syndromes A clinical guide to diagnosis and management

Peter E Baldry

Hardback, Pages: 424, Price: £44.95

**Churchill Livingstone, Harcourt Publishers
Ltd, London 2001**

ISBN 0 4430 7003 2

All you need to know about myofascial pain and fibromyalgia including aetiology, mechanism, presentation, and treatment is contained in this

new reference book by the trigger point guru - Peter Baldry. I much enjoyed his 'Acupuncture, Trigger Points and Musculoskeletal Pain' (second edition, 348 pages), which was published in 1993 and covered all the theory about myofascial trigger points, together with practical applications of acupuncture applied to different parts of the musculoskeletal system.

'Myofascial pain and fibromyalgia syndromes' is set out in similar fashion to the above book, but takes a broader picture, and considers all methods of treatment, as well as deactivation of trigger

points by dry needling, and the arguments of superficial versus deep needling are discussed. The clinical detail of anatomy and pain referral is well illustrated, as well as the presenting history, clinical examination, and differential diagnosis. This makes the book very comprehensive, and of much wider appeal to disciplines outside acupuncture.

The first third of the book covers the background to myofascial pain in terms of its historical discovery, pathogenesis, neuro-physiological mechanisms, and the nature of myofascial pain compared to nociceptive and neuropathic pain. It is all beautifully explained and illustrated.

The remaining two thirds of the book cover the regional myofascial trigger point pain syndromes, starting with the neck and finishing with the anterior abdominal wall and pelvic floor. Each of the chapters goes much further into detail than the

rather strict anatomical coverage of the 1993 book. For example, cervical whiplash and repetitive strain injury were barely mentioned in the previous book, but are now covered from a wide perspective.

The final two chapters of the book cover the fibromyalgia syndrome and were not written by Baldry, but by an American Professor in Rheumatology, and a Turkish doctor from the University Medical School in Ankara. The energetic pace of description continues with these authors to give an excellent summary of fibromyalgia, but medical acupuncturists will be disappointed with little reference to acupuncture treatment.

If your bookshelf has room for just one book on myofascial pain, then this masterpiece of the trigger point is my choice for medical acupuncturists, pain specialists, and musculoskeletal physicians.

Colin Lewis

The Biology of Acupuncture

Ulett GA, Han SP

Paper / Hardback, Pages: 160, Price: \$25.00

Warren H Green Inc, St. Louis, USA 2002

<http://www.whgreen.com>

ISBN 0 87527 534 6

The authors describe their book as “*a scientifically supported explanation of the basic biological mechanisms and processes underlying the practice of traditional Chinese acupuncture*”. They argue that whilst acupuncture is still mainly performed as a mystical ritual, explained in pre-scientific terms of hypothesized meridians, acupuncture points, Qi, Yin/Yang, pulse diagnosis etc, there is now a wealth of scientific knowledge available to support a simpler more effective approach to acupuncture treatment called ‘neuro-electric acupuncture’ (NEAP) or ‘needleless electroacupuncture’. The authors review more than thirty years of stringent research from Beijing Medical University and elsewhere that supports this approach to acupuncture, and reveal the real

meaning and neuro-biological equivalents behind traditional acupuncture practice. The book also claims to be a teaching manual for physicians, by means of which evidence based, no-needle methods of treatment can be easily learned and implemented in clinical practice.

So what does this book tell twenty-first century acupuncture practitioners and physicians about the use of needleless neuro-electric acupuncture, and why should they consider using it in preference to the traditional Chinese needling methods based on so-called ‘obsolescent metaphysics’? The detailed evidence base for neuro-electric acupuncture, in comparison with traditional acupuncture, is clearly set out for the reader to examine, together with guidance on the clinical applications of needleless techniques in practice. So this book is an excellent introduction to the ‘biology of acupuncture’ and the basic principles and practice of scientific neuro-electric acupuncture. Evidence is also presented which suggests that the needleless approach to be just as effective as electroacupuncture through needles, and twice as effective as needling alone. This book should

appeal to all acupuncture practitioners, traditional or modern, as well as physicians and others interested in learning and using a scientific evidence-based approach to acupuncture treatment. Whilst we may not readily agree with everything Ulett and Han have to say in their book, we cannot ignore their stimulating presentation of an important evidence-based contribution to the knowledge and practice of acupuncture.

There may be some difficulty for traditional acupuncture practitioners and others who have spent a considerable amount of time, and

thousands of dollars/pounds, learning traditional pre-scientific concepts and needling techniques, to abandon them for a comparatively simple and evidence-based approach to effective acupuncture treatment. Nonetheless, this book allows us to consider the scientific evidence, to reflect on the issues of acupuncture practice development, and the benefits of this approach for both practitioners and patients. It is well worth reading – who knows, you might even decide to try this approach for yourself.

Gordon Gadsby

The Desktop Guide to Complementary and Alternative Medicine an evidence-based approach

Edzard Ernst (editor), Max Pittler, Claire Stevinson and Adrian White (associate editors)

Paperback, Pages: 444, Price: £24.95

**Mosby, Harcourt Publishers Ltd, London 2001
ISBN 0 7234 3207 4**

The authors, listed as editor and associate editors on the cover, are to be congratulated for producing this thorough and systematic guide to complementary and alternative medicines (CAM). This guide is clearly aimed at the orthodox general practitioner (GP), and is the first of its kind in the field. Those responsible come from the Department of Complementary Medicine at Exeter University, where much of the work of reviewing and documenting the research in CAM has been performed over the last seven or eight years.

The guide comes with a CD ROM version secured within the rear cover. The latter must be removed before the reader can thumb through the text unhindered. Both versions come in six sections that are clearly laid out and easy to navigate. The first section is about using the guide. The second section covers diagnostic methods. It is brief, to the point, and not terribly encouraging for those who use any such methods. The third section gives a brief overview of each of the CAM

therapies for which there was sufficient evidence of effectiveness to warrant inclusion in the guide. Others are listed in a table at the end of this section, with more limited information. The fourth section gives detailed information on herbal and non-herbal medicines. Those with most evidence are covered in detail; others are listed in tabular form. There is information at the end of this section on terminology, toxicology and interactions with orthodox medicines. The latter will be very useful to the busy GP, although the table listing products that require therapeutic monitoring, which includes for example renal function and electrolytes for patients taking cucumber, would benefit from clarification, in terms of the context in which such monitoring was recommended. The fifth section is perhaps the most heroic! Never having been attempted before, the authors put their combined necks on the block by making risk benefit assessments of the main CAM therapies in a wide range of clinical conditions. This was always going to be risky, but in having the courage of their evidence-based convictions, the authors have produced something that is invaluable to the busy GP. The final section covers general topics of interest in CAM, including perspectives from different areas of the western world, why patients seek CAM, legal and ethical issues, safety, and economic issues.

There will undoubtedly be criticism from CAM practitioners who feel that their particular therapy has been overlooked or inappropriately assessed,

and possibly from researchers with a different interpretation of the evidence. As a medical acupuncturist I was quite favourably surprised by some of the assessments, but, of course, the condition we all find responds the best empirically, myofascial pain, is not represented at all. This cannot be seen as a failure of the guide, but a reflection of the lack of appropriate research in this area, combined with a reluctance of orthodox medicine to even embrace the very concept of pain derived from skeletal muscle.

The nature of publishing a reference book, particularly an evidence-based text, in a new and

expanding field, is such that by the time this guide was available further research had been published, some of which may change the recommendations. Perhaps, in the future, this will become a web-based guide subject to regular revisions.

In summary, this is a unique reference book, and I am confident that within a few years it, or a subsequent edition, will become an essential component of the GP's desktop. Indeed, those practitioners with responsibility for the higher socio-economic groups may well find that they come to use this book more than their BNF.

Mike Cummings