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Patient safety incidents from acupuncture treatments: A review of reports to the National Patient Safety Agency

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Abstract. *Background*: Acupuncture is frequently employed to treat chronic pain syndromes or other chronic conditions. Nevertheless, there is a growing literature on adverse events (AEs) from treatments including pneumothorax, cardiac tamponade and spinal cord injury. Acupuncture is provided in almost all NHS pain clinics and by an increasing number of GP's and physiotherapists. Considering acupuncture's popularity, its safety has become an important public health issue.

Objectives: To evaluate the harm caused to patients through acupuncture treatments within NHS organisations.

Methods: The National Reporting and Learning System (NRLS) database was searched for incidents reported from 1st January 2009 to 31st December 2011. The free text fields of all reports received from all healthcare settings and specialties were searched for the keyword 'acupuncture'. All relevant incidents were reviewed to provide a qualitative theme of the harm to patients.

Results: 468 patient safety incidents were identified; 325 met our inclusion criteria for analysis. Adverse events reported include retained needles (31%), dizziness (30%), loss of consciousness/unresponsive (19%), falls (4%), Bruising or soreness at needle site (2%), Pneumothorax (1%) and other adverse reactions (12%). The majority (95%) of the incidents were categorised as low or no harm.

Conclusions: A number of AEs are recorded after acupuncture treatments in the NHS but the majority is not severe. However, miscategorisation and under-reporting may distort the overall picture. Acupuncture practitioners should be aware of, and be prepared to manage, any significant harm from treatments.

Keywords: Acupuncture, patient safety, adverse event, pneumothorax

1. Introduction and background

Acupuncture is one of the best known forms of complementary and alternative medicine (CAM) and is frequently employed to treat chronic pain syndromes or other chronic conditions [1]. Acupuncture has been used for millennia and some proponents claim that this long history suggests safety. However, there is a growing literature on adverse events from acupuncture including pneumothorax, cardiac tamponade, spinal cord injury and viral hepatitis [2–7].

The two main styles of acupuncture practised in the UK are Traditional Chinese and Western Medical Acupuncture. As the majority of acupuncture treatments are provided outside the NHS it is difficult to

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estimate the number of patients who receive acupuncture treatments per year in the UK. Considering acupuncture's popularity, its safety has become an important public health issue.

1.1. Acupuncture in the NHS

The Royal London Hospital for Integrated Medicine, part of University College Hospital NHS Trust, introduced acupuncture into the NHS in 1977. It is currently the largest provider of acupuncture services to NHS patients, with several thousand patient sessions per year. Conventional doctors, nurses and physiotherapists who are trained in acupuncture provide all treatments. Acupuncture is also offered as part of treatment programs at the Glasgow Homeopathic Hospital [8]. Furthermore, acupuncture is provided in almost all NHS pain clinics and by an increasing number of GP's and physiotherapists. Acupuncturists are currently not regulated by statute but several acupuncture organisations exist of which practitioners with certain qualifications can be members voluntarily.

1.2. Scale of the problem

Surveys to determine the frequency of acupuncture-related adverse events (AEs) have been conducted in several countries, e.g. Germany [9, 10], the United Kingdom and Northern Ireland [11, 12] revealed mild, transient adverse events with an incidence rate of 671 to 1510 per 10,000 consultations. The most common AEs were local pain from needling and slight bleeding or haematoma. Other reports, however, showed that acupuncture treatments could also lead to serious, sometimes life-threatening complications [3, 6, 7, 13]. A recent systematic review of case reports, case series and other articles between 1965 and 2009 reported 86 deaths from complications arising after acupuncture treatments. Due to under-reporting, this figure might merely depict the tip of a much bigger iceberg [14]. There are currently no rigorous systems for reporting AEs of acupuncture. Therefore, the number of AEs recorded in the literature is likely to be considerably lower than the true figures.

1.3. Aims of study

This paper is aimed at evaluating the harm caused to patients through acupuncture treatments within NHS organisations.

2. Methods

2.1. The National Reporting and Learning System (NRLS) database

The National Patient Safety Agency (NPSA) collects and analyses reports of patient safety incidents where one or more patients receiving NHS care has been harmed or a near miss incident has occurred. All NHS organisations in England and Wales report these incidents into the NRLS mainly via local reporting mechanisms. The national Patient Safety function, which has responsibility for the NRLS, does not investigate individual incidents but analyses data to identify common risks in order to enable national learning from these incidents and improve patient safety in the NHS. The NRLS as at December 2011 held over 6.6 million patient safety incident reports and receives over 100,000 reports every month.

Table 1
Categories and severity of reported patient safety incidents from acupuncture

Type of AE	Severity of AE				Total
	Severe	Moderate	Low	No harm	
Retained needles	0	2	12	86	100
Dizziness	0	0	30	69	99
Loss of consciousness/ Unresponsive	0	4	34	25	63
Falls	0	1	5	6	12
Bruising/soreness at needle site	0	0	6	1	7
Pneumothorax	1	2	1	1	5
Other adverse reactions	0	5	16	18	39
Total	1	14	104	206	325

2.2. Search strategy

The NRLS database was searched for incidents in a two-year period (1st January 2009 to 31st December 2011). For this period, the NRLS received over 3.7 million patient safety incident reports. Each incident reported to the NPSA has several free text fields in which the reporter is able to describe details of what happened when the incident occurred, the apparent causes and actions that might be taken to prevent a re-occurrence of the incident.

The free text fields were searched for "acupuncture" for all reports received into the NRLS from all healthcare settings and specialties.

All relevant incidents were reviewed by a NPSA Clinical Reviewer in order to provide a qualitative theme of the harm caused to patients as reported in the free text description of the incident. Reports that were unclear or ambiguous were discussed with a second Clinical Reviewer to reach a consensus.

3. Results

The search produced a total of 468 reported patient safety incidents of which 325 met the inclusion criteria for classification (Table 1). The incidents excluded contained "acupuncture" within the free text sections of the report but did not describe harm caused to the patient during or immediately following acupuncture treatment or was felt not to have been directly associated to the AE.

3.1. Retained needles

There were a total of 100 incidents where acupuncture needles were left in the patient longer than prescribed. In 59 of these incidents, the patients (either on their way home or at home) found that a needle had been inadvertently left in place after treatment. Needles that were found in items of clothing were excluded from the review. For the remaining 41 incidents, the patient's treatment period continued, in a few cases for up to three hours longer than intended. Some of these incidents occurred in busy clinics, in cases where several patients were treated simultaneously and when a timer reminding the clinician that treatment was over was not heard or acted on.

Twelve of these incidents recount that the member of staff treating the patient had left the department for a clinical meeting, training session, lunch or even gone home at the end of the day leaving the patient with needles *in situ*. Examples include a patient who was left with needles in situ after the department had been locked up and everyone left for lunch, another patient was found with needles in situ in his upper body over 30 minutes after all the clinical staff had left at the end of the day.

3.2. Dizziness

A total of 99 incidents described the patient feeling dizzy and/or faint without loss of consciousness. There were several reports of patients feeling light headed, hot and nauseous during treatment. Other patients complained of dizziness, feeling wobbly and chest tightness within a few minutes into the acupuncture session.

3.3. Loss of consciousness/unresponsive

Sixty-three incidents related to patients temporary losing consciousness or found unresponsive by the clinician providing the treatment. These incidents were described as "became unresponsive, stopped breathing", "became unwell and fainted", "becoming unresponsive to voice for about 30 seconds" or "slumped to side and fell onto floor ... and lost consciousness and stopped breathing". Twenty (32%) of these incidents required accident and emergency (A&E)/ambulance assessment. Six of these patients also appeared to have suffered a minor seizure. None of the reports described underlying conditions, not related to the acupuncture treatment, as possible causes of the loss of consciousness and many stated that the patient recovered quickly once the needles were removed.

3.4. Falls

There were 12 incidents relating to patients having a fall with one incident resulting in moderate harm. Eight of these incidents described patients falling off the treatment couch during or just after treatment. Three patients were reported to have fallen in the corridor and another patient fell down a step on the way out of the clinic. There were several cases of falls reported in the previous category, where the patient became unconscious or unresponsive and as a result fell onto the floor or slide out of the treatment chair.

3.5. Bruising/soreness at needle site

There were seven incidents where patients suffered bruising or soreness at the site of the needle entry. A patient suffered small blisters over the lumbar spine and at the base of left and right thumbs after treatment.

3.6. Pneumothorax[1]

Five incidents described pain and difficulty in breathing following acupuncture treatments. Two of the incidents, reported as severe and moderate harm were diagnosed as pneumothorax attributable to

[1] Defined as incidents where either this diagnosis was specifically stated or there were clear symptoms indicative of this on clinical review in combination with acupuncture site where pleural puncture was plausible.

acupuncture. At least two of the other three incidents were very likely due to a pneumothorax but remained undiagnosed at the time of the report.

3.7. Other adverse reactions

A further 39 incidents related to AEs other than those discussed above during or immediately after treatment. Some of the reported symptoms included; patients experiencing hot flushes or vomiting, headache or other pains during treatment (not at the immediate needle site).

3.8. Degree of harm

The NRLS grades the degree of harm of patient safety incidents as no harm, low, moderate, severe and death [15]. The reporter of the AE classifies the severity of harm. Therefore, there may be an element of subjectivity as an incident reported as severe is one that "appears to have resulted in permanent harm". Categorisation of incidents by degree of harm in these data showed that 310 (95%) were classified as no or low harm. Of the remaining incidents, 14 (4%) were classified as moderate harm and one case of pneumothorax as severe harm. Incidents relating to loss of consciousness and the patient feeling unwell e.g. stomach pains had a higher incidence of moderate harm. Only two of the incidents describing retained needles were reported as causing moderate harm; one of which required surgical intervention to remove the needle. There were no deaths reported in this search.

There were a total of 29 incidents where the patients required further assessment by ambulance crew and/or were seen in the Emergency Department during or immediately after the acupuncture treatment session. Eight incidents described problems with the emergency procedures in the clinical area in which the acupuncture was provided (e.g. empty oxygen cylinder, call bell not working and lack of clarity regarding emergency procedures). This was particularly apparent in the isolated locations in which some acupuncture clinics are held.

4. Discussion

To the best of our knowledge, this is the first report describing AEs after acupuncture within NHS organisations. A total of 325 AEs were noted within a three-year period. As there is no denominator, an incidence rate cannot be calculated; presumably, it would be relatively low. Thus acupuncture, as practiced in the NHS, seems to be a low harm treatment, considering that only one AE was reported as severe. As the reporter did the classification, it is possible that the severity was understated in some cases and equally possible to have been overstated in others. For instance, there were five cases of pneumothorax, a potentially life-threatening condition; only one was classified as severe and one was even classified as causing "no harm". Similarly, it is possible, even likely that many AEs were not reported at all. Under reporting of AEs is a known problem and there are reasons to assume that it also affects acupuncture.

The nature of the reported AEs is similar as that from other investigations. A systematic review of 9 prospective surveys found that needle pain was experienced by 1–45% of patients, tiredness by 2–41% and bleeding by 0.03–38% [16]. Our investigation revealed only one AE reported as causing severe harm. This is in contrast to case-reports which continue to disclose serious complications and deaths after acupuncture [13]. The apparent discrepancy might be due to the fact that, in our review, all the acupuncturists worked in the NHS and had a first healthcare qualification as well as some acupuncture training, that acupuncture in the NHS is usually practiced within a narrow field of patient's presenting

problems or that the practitioner's original clinical background provides at least a basic standard of patient safety. Training programmes are also well established in the UK, the British Acupuncture Council (BAcC) working closely with the British Acupuncture Accreditation Board (BAA) oversees acupuncture education. Training programme includes 80 hours of basic training and formal assessments. However, this level of training is not required by all NHS organisations. Acupuncturists outside the NHS or outside the UK may not always be well trained and therefore serious AEs might occur more frequently. A review of the Chinese literature, for instance, suggested that acupuncturists in rural China are often poorly trained and therefore a risk factor [7].

Retained needles were the most frequent incident. Although the majority of these incidents were reported as no harm, the distress or inconveniences caused to the patients who are unattended for a couple of hours must be acknowledged. Moreover, only a few reports stated there was a policy on counting needles in and out. We also identified a number of incidents where the emergency call bells or buzzers for clinicians to alert others that they were in need of assistance; a serious shortfall in basic patient safety.

AEs describing dizziness and a temporary loss of consciousness are commonly cited in the acupuncture literature and usually attributed to "needle shock", a vasovagal reaction to needle insertion [17]. A qualitative review of these AEs highlighted a number of incidents in which the patient was described to have been fully assessed and when experiencing an adverse reaction the care and treatment of the patient was exemplary. However, there were also incident descriptions where the practitioner did not respond swiftly to the onset of symptoms in contrast to others where the crash team or an ambulance was immediately called for. Follow up actions also differed widely, ranging from arranging another acupuncture appointment to stopping treatment completely as acupunctured was no longer deemed appropriate following a comparable adverse reaction.

5. Conclusions

A total of 325 patient safety incidents met our inclusion criteria for harm caused by acupuncture treatment over a two year period. Although, only one incident was reported as severe, mis-categorisation and under-reporting may distort the overall picture. Acupuncture practitioners should be prepared to manage all aspects of the patient's care and treatment during acupuncture, conduct full assessments of patients at every session and respond readily to any adverse events following treatment. In particular, the possibility of pneumothorax should be noted.

Practitioners and managers should be responsible for the safe and effective management of acupuncture clinics with adequate consideration of the system within which the treatment is delivered. This can include the emergency procedures available, maintenance of equipment, use of practice drills, timing and length of treatment, counting needles in and out and management of patients within the clinic session. Proactive hazard analysis techniques (such as Failure Modes and Effects Analysis) are useful in planning and assessing the risks of services [18].

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Competing interests

None.

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