

Original article

Adverse events following acupuncture: A prospective survey of 13,884 consultations in a university out-patient acupuncture training clinic in Brazil[☆]

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Abstract

Introduction: Acupuncture is increasingly used in mainstream western clinical practice but its safe use particularly during acupuncture training has not been established. The aim of this study was to identify any adverse events following acupuncture, performed by medical residents in training in the out-patient clinic of the Rio Preto Medical School (Famerp) and to compare the findings with previous literature.

Methods: A prospective observational study was carried out over a period of 28 months as part of clinical practice delivered as part of acupuncture training programme. A serious adverse effect was defined as one which needed specific intervention or interfered with the patient's normal life.

Results: Over the time period there were 13,884 consultations with 1157 patients who had received acupuncture treatment for several pathologies, mainly musculoskeletal diseases. No serious adverse events were identified. The rate of minor adverse events per consultation was 7.97%, the most common were; bleeding (4.1%), pain at the site of needle (3.01%) and itching/redness (0.43%).

Conclusions: Acupuncture provided by physicians, even in a training programme, is a relatively safe treatment. Emphasis must be still given to the knowledge of conventional medicine, the study of anatomy and constant supervision.

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Introduction

Acupuncture has become popular in western countries and is increasingly integrated into conventional medicine, being used for some functional diseases [1,2] and controlling pain [3–5]. In Brazil, acupuncture has been offered within the Public Health System since 1988, and has been a medical specialty since 1995 [6]. In 2004 was created the first Medical Residency Programme

on Acupuncture was created [7]. As a result, colleges and university hospitals have become places to train young doctors in acupuncture. Stimulation of acupuncture points can be applied using laser, seeds, electrodes, magnets and moxa rolls but needles are still by far the most common method but accidents can occur.

Most prospective studies have shown no severe complications [8–10], though some articles have cited unusual dangerous accidents [11,12] such as pneumothorax [13], spinal cord injuries [14], infections [15,16] and even lesions in abdominal viscera [17].

An acupuncture service is provided by the out-patient clinic of Rio Preto Medical School (Faculdade de Medicina de Rio Preto – FAMERP) in São José do Rio Preto, São Paulo State, Brazil. It accommodates medical residents and other young doctors who are undertaking their acupuncture training. Our concern, therefore, as professors, is to be sure that this training is

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safe. The aim of this paper was to investigate the occurrence of any adverse events during doctors training in acupuncture (the type and frequency of event), and compare the results with other studies in the literature.

Methods

This prospective observational study included patients who received acupuncture treatment from doctors training in acupuncture during 2010–2012. Following their first visit, patients were asked, by the professor, about any feeling of discomfort they had experienced and whether they attributed these to their treatment (this report included during and after the treatment). Only reports on traditional needle acupuncture, defined as ‘manual insertion of stainless steel filiform needles into classical acupoints and myofascial trigger points’, retained for at least 25 min and performed by medical residents were included. Data provided from treatment with electro-acupuncture, moxibustion and cupping were not recorded. Adverse effects were defined as ‘any unusual, inconvenient or ill-effect, no matter how small, that is unintended and non-therapeutic’ [18]. Examples were given to patients included: bruises (bleeding with no swelling), hematomas (bleeding with swelling), pain at the site of needle and bleeding (both after leaving the clinic), itching and redness, neuritis (more than 24 h), transient vegetative symptoms (nausea, sweating and vertigo) and forgotten needles. These were classified as ‘mild events’. We did not include ‘aggravation of symptoms’ because of the difficulty in judging whether the event was associated with acupuncture, was serious or not, and also because some practitioners believe that transient worsening is part of treatment. A ‘serious event’ was considered as one which needed further specific medical intervention or had interfered with the patient’s normal life for at least the remainder of the day [19].

The aim was to reach at least 10,000 consultations in order to possibly identify any rare adverse events in order to express the results as rates per consultation rather than per individual patient.

Results

Data were collected over 28 months, from September 2010 to December 2012, by five medical residents, in the out-patient clinic of Rio Preto Medical School (Faculdade de Medicina de Rio Preto – FAMERP) where approximately 30 patients are seen daily. During the 28 months there were a total of 13,884 acupuncture consultations representing 1157 patients.

No serious adverse events were identified. The mild events reported are presented in Table 1.

A total of 1107 events were reported (7.97%). For 12,792 consultations, no adverse events were recorded in 92.03% of consultations. The most commonly reported adverse event was bruising (419 cases (3.01%)), there were an additional 102 cases (0.73%) for haematoma, and 50 cases (0.36%) for bleeding, i.e. giving a total of 571 cases (4.1%). Half (51.5%) of the adverse events reported were related to bleeding and none of these patients were taking anticoagulant drugs.

Table 1

Adverse events following 13,884 acupuncture consultations in 1157 patients.

Adverse events	N	%
None reported	12,792	92.03
Bruises	419	3.01
Pain	419	3.01
Haematoma (with swelling)	102	0.73
Itching and redness	60	0.43
Bleeding	50	0.36
Forgotten needles	33	0.24
Neuritis	15	0.11
Transient vegetative symptoms*	9	0.06
Total consultations with AEs	1092	7.86
Total adverse events	1107	7.97
Total consultations	13,884	100

Obs. nausea (5), sweating (3), vertigo (1).

Pain at the site of the needle was the other most common event and 419 cases (3.01%) identified. A forgotten needle, also counted as an adverse event, which is an indication of negligence and occurred 33 times (0.24%). All reported reactions were mild and transient and no medical care was required. Only fifteen patients had more than one episode of an adverse event.

Discussion

The aim of this study was to identify from our acupuncture patients treated by doctors training in acupuncture, the type and frequency of adverse events experienced and attributed to acupuncture treatment and to discover the level of risk. The possible causes identified permitted the clinical staff to discuss the procedural changes that might minimise these risks in the future. Our concern as professors was to demonstrate that we could provide the best education and supervision to our residents whilst ensuring optimal patient safety.

Methods used to define and document adverse events differ from author to author. It is often uncertain whether a specific event can be correctly attributed to acupuncture but is preferable to be over-inclusive than missing reports and the opportunity to learn [19]. The incidence of adverse events can be described per patient or per consultation, these data were comparable to that reported in the literature. The general rate for adverse events, 7.97% was in agreement with the range described by Zhang et al., 6.71–15% [20]. Other authors arrived at similar figures: White et al., 6.84% [21]; Melchart et al., 7.1% [22]. Using rates per patient and not per consultation, MacPherson et al. has reported in two studies, 13% [23] and 10.7% [9], Witt et al.’s, studies reported, 8.6% [10] and 7.4% [24], and Endres et al., 7.54% [25]. Combining bruising, haematoma and bleeding for our data, the value of 4.1% is comparable with the 6.1% observed by Witt et al. [10], 2.1–6.1% observed by Zhang et al. [20], and the 3.1% seen by White et al. [19], but is less than that of Park’s 8.4% [26]. Pain at the site of needle was similarly to the data reported by Zhang et al., 3.01% [20].

This study identified 15 cases of mild neuritis (lasting more than 24 h and less than 1 week) occurring at the following acupuncture points; LU9 (6), K3 (4), LI4 (2), and PC6 (2) and the worst (around a week) for GB34. A total of 33 cases of

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