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Adverse events during acupuncture training at the 3rd Edition of the Post-Graduation on Medical Acupuncture at Health Sciences School of the University of Minho

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ABSTRACT

Acupuncture is a therapeutic technique in which fine solid metal needles are inserted into the body and manipulated, in order to elicit local, segmental and extra-segmental effects, thus modulating the activity of the Peripheral and Central Nervous System (including the activity of the Autonomic Nervous System). Training on Acupuncture for medical doctors usually involves peer practice of needling throughout the duration of the training program. It is expected that the occurrence of adverse events during training reflects the most common adverse events reported during acupuncture practice. We recorded all of the adverse events reported by the trainees of the 3rd Edition of the medical acupuncture training program of the Health Sciences School of the University of Minho (HSS-UM) and classified them according to the Common Terminology Criteria for Adverse Events (CTCAE, version 4.0, June 2010). The most common events reported, as we expected, were pain and bruising. We conclude acupuncture training is safe, as mostly minor effects occurred during the training program, bruising and pain being the most common. We also concluded that the CTCAE is a valuable tool for classification of acupuncture related adverse events.

1. Introduction

Acupuncture is a therapeutic technique in which fine solid metal needles are inserted into the body, usually onto the muscle tissue, and stimulated manually or electrically, in order to elicit local, segmental and extra-segmental effects, with the objective of modulating the activity of the Peripheral, Central and the Autonomic Nervous System [1].

Acupuncture is a very safe therapeutic technique, especially when its practitioners have training in anatomy and adequate needling technique [2]. Post-graduation training in acupuncture for Medical Doctors at public medical schools in Portugal has started in 2003, and since more than 300 Medical Doctors have been trained. Surface anatomy and safe needling techniques take a large part of the training programs of Medical Acupuncture. Especially, when training in Western Style Acupuncture (WSA), the training in surface anatomy, muscle palpation and testing and deep needling techniques skills are the major components of the training program [3]. Our group has been involved in the training of medical doctors in Acupuncture since 2005, having participated in the development of two WSA oriented post-graduation training programs, at the NOVA Medical School, in Lisbon, and at the HSS-UM, in Braga [3].

During the course, students will practice needling in their peers, under instructor supervision. Needling techniques taught during the Course Program include electro-acupuncture, auriculotherapy, trigger point Dry Needling, needling into para-spinal and abdominal muscles for segmental stimulation, distal needling, both into muscle tissue and also near neuro-vascular bundles. In order to keep needling practice as safe as possible, trainees are required to study the insertion locations anatomy before needling practice. Anatomy and safety concerns are reviewed and the correct needling

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technique is demonstrated prior to needling by the instructors. Needling is performed under instructor supervision, and a ratio of 8 students per instructor is always kept. Needling into locations where risk for traumatic events is greater (near neuro-vascular bundles, arteries or nerves, or over the rib cage) can only be performed under direct instructor supervision. The total number of hours of practice during the training program, for the 24 trainees, is around 720.

From the beginning of the training programs trainees have related adverse events, mostly minor and short-lasting: pain from needling (during and after needling), bruising and other less frequent symptoms. On the 2nd Edition of the Post-Graduation Course at the HSS-UM, we had a major adverse event, a pneumothorax which required exssuflation therapy [4].

After reinforcing safety measures, we decided to have a detailed report of all the adverse events occurring during the next Course, which ran from October 2014 to June 2015 at NOVA Medical School in Lisbon (unpublished results). While reviewing and classifying the reported adverse events we realized the often used classification of minor, significant and severe did not reflect the impact of the adverse event, usually over-estimating it, specially for vascular lesion related events. We decided to use the CTCAE (version 4.0, June 2010) in the next course, which took place between October 2015 and June 2016, at the HSS-UM.

The CTCAE classifies adverse events in five grades, 1–5, according to severity, taking into account the impact on Activities of Daily Life (ADLs) [5]. Grade 1 is used for mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. Grade 2 is used for moderate; minimal, local or non-invasive intervention indicated or limiting age-appropriate instrumental ADL. A Grade 3 adverse event is a severe or medically significant but not immediately life-threatening event; hospitalization or prolongation of hospitalization indicated; disabling or limiting self care ADL Grade 4 is an adverse event having life-threatening consequences or urgent intervention indicated. A grade 5 event results in death.

2. Methods

At the beginning of the course, the trainees were given a digital spreadsheet, and instructed to write down any adverse event that they would experience during or after needling practice. Instructions on how to write down reports were given and they were required to send the written report prior to the beginning of the next Unit, which usually ran 4 weeks apart, allowing time for resolution of most of the events. At the end of the training program the students were required to deliver a full report containing all individual Unit reports.

Any event should be described, even if short-lasting. The report would describe the date and nature of adverse event (bruising, pain, etc) and the location of insertion related to the event (if possible). Severity of pain was registered by a numerical rating scale (NRS), ranging from 0 to10; duration until resolution was also registered. The trainees were also required to report the impact of the adverse event on ADL, and if any medical treatment had been performed. They were required to give a full report for each unit, even when no adverse events had occurred. All trainees provided written consent for data collection and treatment.

After completion of the Course, all trainee spreadsheets were compiled into a single spreadsheet and classified according to type of event, severity and impact on ADLs. Pain was classified as mild (NRS 1–3), moderate (NRS 4–6) or severe (NRS 7–10).[1] Impact on ADLs was classified as "no limitation", "limiting age-appropriate instrumental ADLs" and "limiting self care ADL". Each adverse event was then classified according to type of adverse event and severity, as defined in the CTCAE. We also registered the duration of the events to resolution, and divided them into 6 categories: during needling (up to needle withdrawal), up to one hour after needling, from 1 h up to 1 day after needling, from 1 day up to one week after needling, from 1 week up to 2 weeks and from 2 weeks up to one month after needling.

Table 1
Distribution of the reported adverse events in each Unit.

Unit	Frequency	Percent
U 1–2	36	22,4
U 2	18	11,2
U 3-1	20	12,4
U 3-2	8	5,0
U 4-1	15	9,3
U 4-2	15	9,3
U 5-1	31	19,3
U 5-2	18	11,2

U—Unit number. Frequency—number of reported adverse events reported per Unit. Percentage—percentage of reported adverse events per Unit.

3. Results

The sample was obtained from the reports of the 24 trainees, 19 (79,2%) were female; mean age 31,46+/− 5,30 years minimum age 27, maximum age 48. All the trainees were medical doctors (family medicine (9, 37,5%), anesthesiology (8, 33,3%), physical medicine and rehabilitation (6, 25%), rheumatology (1, 4,2%), 1 general medicine (1, 4,2%)).

Records were retrieved from all the 24 trainees. A total of 161 adverse events were reported. Out of the 24 trainees, adverse events were reported by 23 of them. Adverse events were reported in every unit that involved needling workshops. The most frequently reported events were pain related (n = 100 events, 62,1% of all the events), the second most common event was related to vascular lesion (n = 51, 31,7% of the total number of events). Other less frequent events were neurological symptoms (n = 8, 5% of the total number of events), one event related to gastro-intestinal system, and one episode of vertigo (representing each 0,6% of the total number of reported adverse events).

3.1. Distribution by unit and trainee

Thirty-six adverse events were reported during Unit 1–2 (the first Unit with needling practice in the course program; manual needling and electro-acupuncture introductory techniques are taught), representing 22,4% of the total reported adverse events. The second higher number of reported adverse events was recorded in Unit 5-1 (31 adverse events, 19,3%; lower back, hip girdle and lower limb needling techniques) and the third higher number of adverse events was reported in Unit 3-1 (20 adverse events, 12,4%; segmental needling, para-spinal, abdominal, head and distal needling and auricular needling). Table 1 resumes the frequency and percentage of adverse events in each Unit.

One trainee reported 20 events (accounting for 12,4% of the total number), the second highest number of adverse events reported by a single trainee was 17 (10,6%). Four trainees reported only 2

[1] As defined in "Assessment of pain, H. Breivik; P. C. Borchgrevink; S. M. Allen; L. A. Rosseland; L. Romundstad; E. K. Breivik Hals; G. Kvarstein; A. Stubhaug, Br J Anaesth. 2008;101(1):17–24". http://www.medscape.com/viewarticle/580952_2