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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A B S T R A C T
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.

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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

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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 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 exsufflation 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.

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

<table>
<thead>
<tr>
<th>Unit</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>U 1–2</td>
<td>36</td>
<td>22.4</td>
</tr>
<tr>
<td>U 2</td>
<td>18</td>
<td>11.2</td>
</tr>
<tr>
<td>U 3–1</td>
<td>20</td>
<td>12.4</td>
</tr>
<tr>
<td>U 3–2</td>
<td>8</td>
<td>5.0</td>
</tr>
<tr>
<td>U 4–1</td>
<td>15</td>
<td>9.3</td>
</tr>
<tr>
<td>U 4–2</td>
<td>15</td>
<td>9.3</td>
</tr>
<tr>
<td>U 5–1</td>
<td>31</td>
<td>19.3</td>
</tr>
<tr>
<td>U 5–2</td>
<td>18</td>
<td>11.2</td>
</tr>
</tbody>
</table>

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

(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 hour 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.

### 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 to 10; 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]

### 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

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adverse events and one did not report any adverse event. Chart 1 resumes the distribution of adverse events by each trainee.

3.2. Distribution by severity according to the CTCAE

Table 2 resumes the frequency and classification of severity (according to the CTCAE) of the reported adverse events in each Unit. Only 158 of the reported adverse events were classifiable, 3 (1.9% of the total events) were excluded from the severity analysis due to missing data on the report sheet (missing NRS for pain or impact on ADL). The reports were classified from 1 to 3 in the CTCAE severity scale. 103 events were classified as CTCAE grade 1 (65.2%), 48 events were classified as CTCAE grade 2 (30.4%) and 7 events were classified as CTCAE grade 3 (4.4%). All 7 CTCAE grade 3 events were pain-related, either during or after needling. Table 3 summarizes duration of adverse events and impact on ADLs.

3.3. Type of adverse event

3.3.1. Pain

3.3.1.1. Intensity of pain. Pain was the most reported adverse event. Out of the 100 pain related adverse events, 99 were described as muscle-skeletal pain and 1 described by the trainee as headache. The medium NRS reported was 3.88+/− 1.57, mode 3, median 4. Minimum NRS was 0, maximum was 8. Chart 2 depicts the histogram of the reported NRS of the pain related adverse events.

Table 3

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Duration of event</th>
<th>Impact on ADL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>During needling</td>
<td>Up to 1 h</td>
</tr>
<tr>
<td>Headache</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MSK pain</td>
<td>51</td>
<td>12</td>
</tr>
<tr>
<td>Vertigo</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Nausea</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ecchymmosis</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Bleeding</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Pre-syncope</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Paresthesia</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Somnolence</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>64</td>
<td>17</td>
</tr>
</tbody>
</table>

Duration of adverse effect was missing in 8 reports. Impact on ADL was missing on 16 reports.
3.3.2.1. Duration of pain. Out of the 100 pain related events, 51 (51%) only experienced pain during needling up to needle withdrawal. 12 (12%), experienced pain up to one hour after needle withdrawal, 14 (14%) experienced pain up to 1 day after needle withdrawal, 19 (19%) experienced pain up to one week after needling.

3.3.1.3. Impact on ADLs. 8 adverse events had impact on instrumental ADL 77 events reported no effect on ADLs and in 15 events impact of ADLs were missing (see Table 3 above).

3.3.1.4. Need for medical treatment. In the large majority of these events, no specific medical treatment was needed. Only in 6 situations medical treatment was used, in 90 events no treatment was required (in 4 events medical treatment necessity was missing). The treatments used were acetaminophen, NSAIDs and ice. Electro-stimulation and massage were also used each in one case.

3.3.1.5. Classification of severity of pain by the CTCAE. According to the CTCAE, severity of pain related adverse events was classified as grade 1 for 43 events, grade 2 for 47 (one of which was the headache event), grade 3 for 7 events (Table 4). 3 cases were not classifiable due to missing data.

3.3.2. Vascular lesion
51 events (31.7%) were classified as vascular lesions. Bleeding, ecchymosis and hematoma were reported. The most common event was hematoma (22; 13.7% of total events), followed by ecchymosis (21; 13% of total events) and the least frequent was bleeding (8; 5% of total events).

3.3.2.1. Duration of event. 8 events (15.7% of vascular lesions) were bleeding at needle withdrawal. Ecchymosis duration was: 1 event (2% of vascular lesions) lasted less than 1 day, 16 events (34% of vascular lesions) lasted less than 1 week, 3 (5.9%) events lasted up to 2 weeks. Out of the 20 reports of hematoma, 1 event (2% of vascular lesions) resolved right after needle removal and hemostasis, 14 events (27.5% of vascular lesions) lasted up to 1 week, 4 events (7.8%) lasted up to 2 weeks and 1 event (2%) lasted up to a month till resolution; in 3 events, duration till resolution was missing (see Table 3 above).

3.3.2.2. Impact on ADLs and need for medical treatment. All bleeding and ecchymosis events had no impact on ADL. From the 22 hematoma events, 3 had an impact on instrumental ADL. None of the bleeding and ecchymosis events required medical treatment.

3.3.2.3. Classification of severity of vascular lesion by the CTCAE. All vascular lesions were classified as grade 1 by the CTCAE.

3.3.3. Neurological symptoms
8 events (5% of total events) were neurological symptoms. The most frequently reported symptom (5; 3.1% of total events) were paresthesia, 2 (1.2% of total events) were somnolence. Pre-syncopal was reported once (0.6% of total events).

Out of the 5 paresthesia events, 2 resolved at needle withdrawal, the other 3 resolved up to one hour after. Duration of somnolence was reported only by one trainee, and lasted up to one hour after needling. Pre-syncopal symptoms lasted up to one hour after needle withdrawal (about 10 min). 7 of these events had no impact on ADL (1 missing). Classification CTCAE: pre-syncopal was graded as 2, all other 7 neurological events were graded as 1.

3.3.4. Digestive symptoms
Nausea was reported once (0.6% of total events). It lasted up to one hour (about 10 min) after needle withdrawal and had no impact on ADL. No medical treatment was needed. CATCE graded the event as grade 1. It resulted from needling into the medial forearm (for medial epycondilar pain).

3.3.5. Ear and labirinth disorders
Vertigo was reported once (0.6% of total events), lasting up to needle withdrawal, had no impact on ADL. There was no need for medical treatment, the classification according to CATCE is 1. It resulted from needling into the temporals muscle (Taiyang EX-HNS5).

4. Discussion
Acupuncture, or Dry needling techniques, pose a risk for the occurrence of adverse events. The most common are pain, during or after needling, and bruising [6,7]. These events are usually classified as minor events. That has also been our experience while teaching acupuncture to medical doctors in Portugal, at two different universities based training programs [3].

At the 2nd Edition of the Medical Acupuncture Post-Graduation training program at the HSS-UM we had a significant adverse event, a pneumothorax requiring exsufflation therapy [4]. At the end of the course the faculty decided to reinforce safety measures, in order to increase safety for trainees during practice, as it includes extensive needling practice, trainees needling each other under instructor supervision. As part of the safety measures we decided

<table>
<thead>
<tr>
<th>Unit</th>
<th>CTCAE</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Headache</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>MSK pain</td>
<td>43</td>
<td>46</td>
</tr>
<tr>
<td>Total</td>
<td>43</td>
<td>47</td>
</tr>
</tbody>
</table>

2 The CTCAE grades pre-syncopals only as grade 2
3 NMS nomenclature of extra points, accessed in http://apps.who.int/medicinedocs/en/d/Jh2947e/4.5.html#Jh2947e.4.5
to have a complete report of all adverse events occurring during the training program. In the 5th Edition of the NOVA Medical School Post-Graduation Course in Medical Acupuncture, which followed the 2nd edition at HSS-UM, we collected reports of adverse events from 30 out of the 32 trainees. During the data review we realized there was no universally accepted classification system for acupuncture related adverse events. We also found that the classification system we had used (classifying adverse events in minor, significant and severe) was not suited for the classification of acupuncture related adverse events, specially the ones related to vascular lesion, in which severity would almost always be over-estimated, for it relied on time to resolution of symptoms as one of the main parameters for grading. It also did not include the impact of the adverse event on the activities of daily living, which we found to be a major fault.

We looked at different classification systems for adverse events, and we decided to use the Common Terminology Criteria for Adverse Events, as it provides an easy to apply classification system, relying on severity (in case of pain related adverse events), impact of ADLs and need for medical treatment as main parameters for classification. It also provided simple parameters for classification for the most common adverse events related with needling.

The total number of reported adverse events (161), related to the estimated total number of hours of needling practice (720), was about 1 per 4.5 h of needling practice.

The most commonly reported adverse event was pain. Out of the total number of pain related events, about half of these were pain only during needling, which could be attributed to the DeQi sensation, a common occurrence during acupuncture [8]. Of all the pain related adverse events, only 7 were classified as CTCAE grade 3 (severe or medically significant), all due to the reported severity of pain.

Vascular lesion was the second most frequently reported adverse event, with about the same number of hematomas and ecchymosis. All of the events were classified as grade 1. Notably, if the classification system relied on duration to resolution, some of these events would have been classified as more significant than with the CTCAE, for some lasted up to two weeks.

The third most common adverse event reported was paresthesia, resolving at needle removal or up to one hour. Other events (somnolence, pre-syncpe, nausea) are also reported in current adverse events reviews [6,7]. We did not find vertigo as an adverse event related to acupuncture in our bibliographic research.

The frequency of adverse events was higher in two of the training units, unit 1–2 and unit 5–1. We attribute this to the following reasons:

- More extensive needling workshops, either in duration or number of needle insertions in these units
- Inexperience of the trainees in Unit 1–2.

Limitations of this study are: the relatively small number of trainees, report was voluntary thus under-reporting is possible to have occurred. Perception of relevance of the adverse events, specially pain, may vary during the training program, leading to over-reporting in the beginning, and under-reporting at the end of the course. Pain was the most frequent adverse event; as a subjective symptom individual variability of pain perception may influence reporting of incidence and intensity of pain. Use of the numerical rating scale for pain reporting may also be a confusing factor, with influence on grading of severity according to CTCAE.

The questionnaire allowed open answers, which could lead to interpretation bias from the trainees while filling in the answers and also by the researchers (which may have accounted for some of the missing data).

To the best of our knowledge, this is the first systematic report of adverse events related to needling during acupuncture training. The data collected showed a relative small incidence of significant adverse events. In this edition of the training program there were no life-threatening events or sequelae. The impact on ADLs from needling was only on instrumental ADLs.

The CTCAE is, in the authors perspective, a useful and easy to apply tool for the classification of acupuncture related adverse events, even if it is not validated for use in acupuncture.

The severity and type of the adverse events reported by the trainees mirrors the reviews of acupuncture related events [6,7]. We believe that sound knowledge of anatomy [2] and supervision of needling during training are important factors of safety [3,4] during acupuncture training, specially when deep needling or needling over the rib cage, supra-clavicular regions, and near neuro-vascular bundles is performed [2]. We also believe that by having a report system as described in this paper, students become more aware of the possibility of adverse events during needling, possibly leading to a safer learning environment and to a safer practice in the future.

Acknowledgment

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References