

# Acupuncture Adverse Events in China: A Glimpse of Historical and Contextual Aspects

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## Abstract

The article by He and colleagues, “Adverse Events Following Acupuncture: A Systematic Review of the Chinese Literature for the Years 1956–2010” is an important and timely contribution. In this commentary, the article is reviewed and issues are highlighted about how to interpret and contextualize the results of their study. While their review has been well performed, certain areas have been identified where the results may be inaccurate due to problems in the reporting of original incidents. For example, potential problems were found in the reporting of the minor adverse event (AE) of fainting and the more serious AEs of pneumothorax and hepatitis. The article by He and colleagues highlights the issue that almost all AEs associated with acupuncture in the modern period are due to the administration of the therapy rather than the therapy itself. Future prospective studies can address some of the shortcomings identified in this review.

## Introduction

**I**N LATE 2012, HE AND COLLEAGUES published an important article about acupuncture adverse events (AEs) in China during the years 1956–2010.<sup>1</sup> The authors would like to comment on this article, but first it is necessary to share some important aspects influential to reporting and understanding of acupuncture AEs.

### The History of Safe Acupuncture Practice

Discussions of anatomical studies to decide needling depths for the meridians of acupuncture can be found in the *Neijing* (circa 100 BCE),<sup>2–5</sup> with generally shallow needling recommended compared to more recent periods.<sup>6–9</sup> In the *Neijing*, there are many descriptions of needling techniques, including the application of deep needling with rather thick needles.<sup>10</sup> However, acupuncture point locations were unclear and not standardized, which prompted the *Zhenjiu Jiayijing* author in 280 CE to describe location and needling depths of each point systematically.<sup>11</sup>

Several centuries later, acupuncture had developed the reputation of being a dangerous therapy that could kill patients.<sup>12,13</sup> This is not surprising, since knowledge of safe needling based on anatomical considerations was centuries away, as well as knowledge of microbial infections and the risk of cross-infection when reusing nonsterilized needles. In the 11th century, acupuncture was rehabilitated with regard to standardization and improved education.<sup>14</sup> It was

theorized that acupuncture was dangerous because its use was not standardized and the location of the acupuncture points were nonstandard.\* The bronze statue text and model of *Wang Weiyi* (1027 CE) also helped establish clear testing methods to ensure standardized training and testing, which was used as a standard for further practice for some time afterwards. However, descriptions of historical acupuncture practice were still not made with consideration of modern germ theory; for example, the *Zhenjiu Dacheng* in 1601 described: “Place the tip of the needle in the mouth to keep it warm.”<sup>16</sup> Despite the fact that nonsterile needles were used and detailed knowledge of internal anatomy was still centuries away, acupuncture lost its reputation as being a dangerous therapy and became more popular again.

In the modern period, knowledge of internal anatomy is now pervasive in acupuncture training programs, as is knowledge of infection control.<sup>†</sup> Since the 1980s following the rise of the acquired immune deficiency syndrome, disposable single-use acupuncture needles were developed and came into widespread use. However, given the relatively recent appearance of disposable needles and the fact that

\*Other examples related to safety of acupuncture from the historical literature are given by Lao,<sup>15</sup> showing a longstanding tradition of attention to safety issues in the practice of acupuncture.

†These became required study in the late 1940s in Japan<sup>17,18</sup> and in the 1950s in China<sup>19</sup>; see Birch and Felt.<sup>20</sup>

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acupuncture has been used in many places where resources are likely to have been inadequate for proper infection control procedures of re-usable needles, we can suspect that cross-infection will still have occurred, but often due to practitioner negligence. Furthermore, needling in the modern period has become generally deeper than in historical periods,<sup>21</sup> with considerable variation in China between the publications of different Traditional Chinese Medicine (TCM) colleges<sup>22,23</sup> in different regions of China.<sup>\*,23–25</sup> It can thus be suspected that there might be regional variations in the depth of needling both within China and outside China. This variation could contribute to accidents due to improper needling depths with punctured organs or other structures. Finally, there have been periods of time in modern China when safety may not have been sufficiently addressed or acknowledged in the practice of acupuncture,<sup>1</sup> as has happened in the West.

Consequently, it is suspected that there might be adverse events (AEs) due to lack of access to proper infection control in poor, underequipped regions, due to regional and personal variations in needling styles and depths, due to improperly trained people administering acupuncture, and due to the mistakes or negligence of practitioners. Can the large study from China “Adverse events following acupuncture: A systematic review of the Chinese literature for the years 1956–2010,”<sup>1</sup> tell us about these risks and events?

### Definitions

The diversity of techniques and methods that are listed under “acupuncture” raises questions about the definition of acupuncture.<sup>26–30</sup> He and colleagues do not define acupuncture clearly, which makes it difficult to attribute reported cases of AEs to acupuncture, rather than AE due to, for example, minor surgical interventions used within China in the practice of acupuncture.<sup>31</sup>

He and colleagues have used the following definition for acupuncture AEs: “Any unfavourable and unintended sign, symptom, or disease that presents during or after treatment with acupuncture regardless of causal relationship,”<sup>1</sup> similar to U.S. definitions published by the National Institutes of Health (NIH).<sup>32</sup> However, the NIH defined five grades of AE ranging from “Grade 1 Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated” to “Grade 5 Death related to AE.”<sup>32</sup> What definitions of AEs were used in China, in the period 1956–2010 in reports included by He and colleagues? This is likely to be a limitation for any retrospective review of the literature.

### Attribution of Causality to Acupuncture as a Therapeutic Method

In the eighth century in China when acupuncture was thought to be a dangerous and lethal therapy, puncturing of organs and infections due to needling were probably part of

acupuncture practice since infection control and anatomy were not yet known, and thus acupuncture can be said to have been dangerous then. However, in the modern period with widespread knowledge of anatomy and infection control, puncturing of organs through improper needling depth and transmission of infectious disease might not be a risk of acupuncture *per se*; rather, they are problems of practitioner negligence, malpractice, or improper training. More attention needs to be given to ensure clear statements regarding whether the problems were related to the therapy or the therapist. Lewith and White also raise difficult questions about the attribution of AEs with acupuncture when many of the same AEs were found to occur with a sham intervention in a randomized controlled trial.<sup>33</sup> This suggests that some events that are considered AEs due to acupuncture may actually be due to the context and other factors, not acupuncture *per se*.

What are we to make of events that are classified as AEs but that are minor and that are expected from the intervention? Do one list pain, difficulty moving, and bleeding as AEs of a surgical procedure, given that of necessity the surgical procedure produces these effects? By the same logic, inserting a needle will necessarily cause some small local trauma, often have sensations associated with it, some of which will be painful or uncomfortable, and can have a small amount of bleeding associated with it. Does it really make sense to classify these expected and normal reactions to needle insertion as AEs of acupuncture? One report captured short-term effects of treatment that were often seen as positive by patients; should these effects (e.g., feeling relaxed or energized) be classified as adverse events?<sup>34</sup> Is this more an issue of patient information or informed consent rather than AEs?

Furthermore, cases of acupuncture AEs might also have been presented in a misleading way. In the case of cardiac tamponade, the death of an 82-year-old woman from the self-insertion of a sewing needle into the chest<sup>35</sup> keeps being cited as a case of death by acupuncture.<sup>36–38</sup> This event is not the result of correctly practiced acupuncture over the heart region,<sup>39</sup> and it is questionable to attribute events like this to acupuncture.

### The Results from the He et al. Study Compared with Other Studies

#### Fainting

According to He et al.’s article, there were 468 cases of syncope, 45% of the total number of AEs during 1956–2010 come from only 17% of the included articles.<sup>1</sup> However, no articles reporting syncope were published within the 1950s or the 1960s, yet pneumothorax and deaths started to be reported during the 1950s. This could imply a possible bias in the reporting of AEs. Perhaps adverse events are badly reported in original articles and were rarely the focus of research studies.

Fainting might not be considered a serious AE associated with acupuncture, but is more significant than temporary dizziness or temporary pain associated with any needling. Table 1<sup>40–47</sup> shows reports of fainting in the He et al. study alongside reports from prospective studies.

In Table 1 it can be seen that the rate of fainting varies greatly across different studies; however, it is generally more

\*The Shanghai college of TCM published an acupuncture text in 1974 that was translated and published in English in 1981 as “Acupuncture, a Comprehensive Text.”<sup>23</sup> This text prescribes significantly deeper needling than other TCM college texts: the mean and (median depth) across all acupoints (in *cun*) is 1.03 (0.85)<sup>23</sup> compared to 0.57 (0.5)<sup>22</sup> and 0.60 (0.60)<sup>24</sup>; see Birch and Felt.<sup>25</sup>

TABLE 1. COMPARISON WITH RATES OF 'FAINTING' IN PROSPECTIVE STUDIES

Study	Country of study	Number/treatments	Incidence rate (%)
He et al. 2012 <sup>1</sup>	China	468/1,500,000,000 <sup>a</sup>	0.0003
Chen et al. 1990 <sup>40</sup>	Taiwan	55/28,285	0.194
Yamashita et al. 1999 <sup>41b</sup>	Japan	0/65,482	0
Yamashita et al. 2000 <sup>42b</sup>	Japan	0/1441	0
Park et al. 2010 <sup>43b</sup>	Korea	0/3071	0
MacPherson et al. 2001 + 2001 <sup>44,45b</sup>	U.K.	4/34,407	0.012
White et al. 2001 <sup>46</sup>	U.K.	6/31,822	0.019
Witt et al. 2011 <sup>47</sup>	Germany	62/2,200,000 (treatments) 62/229,230 (patients)	0.003 0.027

<sup>a</sup>This number of 1.5 billion treatments is probably very conservative.

<sup>b</sup>The authors distinguish between the milder "feeling faint" and the more severe "fainting." The numbers here are for reports of actual fainting.

often noticed in studies from Western countries. It would be expected that the more intense the needling the greater the risk of fainting. Thus, since needling in the West is generally milder than in China,<sup>28,48</sup> one could expect to see a lower rate of fainting in the West than in China, which is what is seen in relation to the Taiwanese study<sup>40</sup> but not the current study of He and colleagues. Furthermore, since needling is generally milder in Japan than in the West,<sup>28,48,49</sup> we can also expect to see a lower rate of fainting in Japan compared to the West, which is what is found. It is therefore suggested that the number of cases of fainting in the He et al. study are underestimated, possibly by a hundredfold or more.

#### Pneumothorax

Pneumothorax is the most frequent reported serious AE associated with acupuncture. Table 2 shows reports of pneumothorax from the He et al. study compared to reports from prospective studies.

Given that pneumothorax can occur in the hands of someone well versed in anatomy<sup>47,50,51</sup> and that needling in China has been generally more deeply compared to Western countries,<sup>28,48</sup> it seems likely that the incidence of pneumothorax in the He et al. study is underestimated due to under-reporting.\* Table 3<sup>54-58</sup> examines the recommended depth of needling for two acupuncture points implicated in pneumothorax in different acupuncture textbooks. A lot of variability of recommended needling depths can be seen, especially of BL-13,<sup>23</sup> which could be problematic with a higher risk of pneumothorax. There is a need for greater standardization of safe needling depths for acupoints that could cause pneumothorax if needled too deep. We agree with Chou et al. that studies should be done to accomplish this.<sup>59</sup>

#### Hepatitis

Hepatitis B is a highly contagious disease, and countries such as China have a moderate-to-high risk of infection compared to many Western countries.<sup>60</sup> Much the same is the situation with regard to hepatitis C.<sup>61</sup> In the West, especially before the regular introduction of disposable needles by the late 1980s, there were a number of outbreaks of

hepatitis associated with acupuncture practices.<sup>38</sup> With greater awareness of the risks, better handling of needles, and routine use of disposable needles, hepatitis has become a rare problem associated with acupuncture in European, North American, and Australasian countries.<sup>38</sup>

The He et al. study<sup>1</sup> has no reports of hepatitis infection associated with acupuncture. Practitioners in China have probably used acupuncture to a greater degree since 1956 than in any other country.<sup>1</sup> It is reasonable to assume that use of nondisposable needles has caused hepatitis associated with acupuncture during the period covered by the study. Thus, it is suspected that the study has not been able to capture data on this serious AE occasionally associated elsewhere with acupuncture. Asian countries are at moderate-to-high risk of hepatitis; thus, it is possible that infections may not have attracted attention, as the prevalence may have been relatively high to begin with.

#### Conclusions and Recommendations

Other studies can be found on acupuncture-associated AEs in China,<sup>62-64</sup> but none are so comprehensive. The article by Zhang et al. reviews journal databases for the period 1980-2009,<sup>63</sup> and the other two articles are reports of AEs

TABLE 2. COMPARISON WITH RATES OF PNEUMOTHORAX IN PROSPECTIVE STUDIES

Study	Country of study	Number/treatments	Incidence rate (%)
He et al. 2012 <sup>1</sup>	China	307/1,500,000,000	0.0002
Yamashita et al. 1999 <sup>41</sup>	Japan	0/65,482	0
Yamashita et al. 2000 <sup>42</sup>	Japan	0/1441	0
Park et al. 2010 <sup>43</sup>	Korea	0/3071	0
MacPherson et al. 2001 + 2001 <sup>44,45</sup>	U.K.	0/34,407	0
White et al. 2001 <sup>46</sup>	U.K.	0/31,822	0
Witt et al. 2011 <sup>47</sup>	Germany	2/2,200,000 (treatments) 2/229,230 (patients)	0.00009 0.0009
Melchart et al. 2004 <sup>50</sup>	Germany	2/ >760,000 (treatments) 2/97,733	0.00026 0.002

\*There are also problems of causality and pre-existing conditions that need to be dealt with in cases of pneumothorax reports.<sup>52,53</sup>

TABLE 3. COMPARISON OF RECOMMENDED NEEDLING DEPTHS OF ACUPOINTS IMPLICATED IN PNEUMOTHORAX

Acupoints	Jiayi <sup>a</sup> (280)	Tongren <sup>a</sup> (1027)	Dacheng <sup>a</sup> (1601)	Cheng <sup>ab</sup> (1987) <sup>24</sup>	So <sup>ab</sup> (1985) <sup>54</sup>	O'Connor <sup>ab</sup> (1981) <sup>23</sup>	Anon. <sup>ab</sup> (1980) <sup>22</sup>	Mori <sup>b</sup> (1976) <sup>55</sup>	Deadman <sup>ab</sup> (1998) <sup>56</sup>	Hecker <sup>ab</sup> (2005) <sup>57</sup>
BL-13 <sup>c</sup>	0.66 cm	1.1 cm	0.66 cm	1.54 cm	1.1 cm	3.3 cm	1.1 cm	2 cm	2.2 cm	1.1 cm
GB-21 <sup>c</sup>	1.1 cm	1.1 cm	1.1 cm	1.1 cm	0.55 cm	2.2 cm	2.2 cm	2 cm	2.2 cm	2.2 cm

<sup>a</sup>The depths are given in “*cun*,” the “body inch.” Chinese authors have estimated the *cun* to be approximately 2.23 cm,<sup>58</sup> while Harper estimated that the *cun* was about 2.31 cm [Harper, D. The “*Wu Shi Erh Ping Fang*”: Translation and Prolegomena. Doctoral thesis, Berkeley, CA: University of California, 1982]. We have adjusted the numbers based on 1 *cun* = 2.2 cm.

<sup>b</sup>These texts gave a range of indicated depths. We took the maximum depth from that range, as this is the one at most risk.

<sup>c</sup>Some modern texts give clear cautions about safe needling depths for these acupoints.<sup>56</sup>

that occur in acupuncture clinical trials. He and colleagues<sup>1</sup> reviewed journal databases over a much larger time frame (1956–2010) and reviewed more databases than Zhang et al. (four versus three). The Zhang et al. publication allows us a point of comparison to the findings in He and colleagues’ article, but clearly the latter makes a large contribution to our understanding of the safety of acupuncture in China.

He and colleagues used the guidelines for judging acupuncture AEs developed by Peuker and Fuller.<sup>65</sup> Although it is impossible to eliminate subjective judgment in the application of such guidelines, they appear to have used them well. The judgments appear reasonable and their explanations about causality seem appropriate. However, they concluded “Acupuncture-related adverse events are mainly caused by mental tension of the patient, improper operation of the doctor and incompleteness of sterilization. Most of the adverse events can be avoided by standardizing teaching and clinical practices.”<sup>1</sup> We are not convinced about these conclusions and recommendations.

In cases of organ puncture, cross-infection, and death, He and colleagues identify problems of practitioner training or practice in almost all cases, as we find in other acupuncture AE studies. However, no other studies or surveys of acupuncture AEs have ever reported that the “mental tension of the patient” was a cause of the events. This may be an interpretation rooted in cultural differences between modern China and elsewhere and that may not be helpful or applicable outside of China.

The statement that “Most of the adverse events can be avoided by standardizing teaching and clinical practices” may also be problematic. We agree that it is very important to ensure good education about anatomy, physiology, pathophysiology, infection control, handling of patients, and so on. We agree that there needs to be standardization and agreement for the application of needles on certain regions of the body or on certain patients, regarding safe needling depths, and handling of treatment techniques. Acupuncture is a highly diverse field of practice with a wide variety of techniques and treatment approaches. Restrictions of these techniques and approaches in light of safety issues (e.g., safe needling depths) should be standardized, but not the teaching and clinical practice systems themselves. We also find reason to doubt the reported rates of fainting, pneumothorax, and hepatitis reported in the study by He and colleagues.

It is difficult in a retrospective review to avoid including double publications. The study reports on 64 cases of subarachnoid hemorrhage but references 105 and 107 look similar to us. Hence, the cases for subarachnoid hemorrhage

may be too high. In reporting pneumothorax, there are a lot of single case reports. However, there are also articles reporting 38 (reference 46) and 92 (reference 86) cases of pneumothorax during the 1980s. Have these and other cases been controlled for double publications?

In order to help with improved safety standards for the practice of acupuncture, it is important to do more prospective studies. Examples are additional studies in safe needling depths, especially of points implicated in problems<sup>59</sup> or in patients more at risk of complications.<sup>66</sup> Following this excellent study by He and colleagues, we recommend the need for large prospective studies of safety and adverse effects in China in order to identify more precisely complications from actual clinical practice and to examine the impact of improved educational standards.

#### Disclosure Statement

No competing financial interests exist.

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