

# Ecchymosis combined with postinflammatory hyperpigmentation associated with acupuncture therapy

## An observational study of 167 subjects

Yuwei Zhao, MM<sup>a,b</sup>, Jinna Yu, MD<sup>a</sup>, Sixing Liu, MB<sup>c</sup>, Jing Zhou, MD<sup>a</sup>, Jing Wang, ED<sup>e</sup>, ZhaoBo Wang, MM<sup>d</sup>, Zhishun Liu, MD<sup>a,\*</sup>

### Abstract

To evaluate the incidence of ecchymosis combined with postinflammatory hyperpigmentation (ECPH) over the course of 10 sessions of acupuncture therapy and to examine associated factors.

An observational study was conducted from March 7, 2017 through March 6, 2018. This study included a total of 167 subjects and 326 bodily locations where acupuncture needles had been inserted. A 1-page questionnaire that included 14 items was used to collect patient data. The information collected was used to determine the incidence of ECPH. Chi-square tests were used to observe the associations between ECPH and demographic characteristics, dermatologic features, acupuncture-related factors, and other associated factors. Cox proportional hazards regression models were applied to calculate hazard ratios for ECPH among subjects treated with various frequencies of acupuncture and needles that differed in diameter.

Although 186 subjects were initially enrolled, the study ultimately included 167 subjects and 326 bodily locations at which acupuncture needles were inserted. Over 10 sessions of acupuncture, ECPH was observed in 117 (70.06%, 117/167) subjects and 221 (67.79%, 221/326) bodily locations. Factors found to be associated with ECPH included: frequency of acupuncture, diameter of acupuncture needle, total number of acupuncture sessions, and bodily location at which acupuncture was administered ( $P < .05$ ). Among subjects who received  $>2$  acupuncture sessions per week, a higher frequency of acupuncture was associated with increased incidence of ECPH. Thicker acupuncture needle diameter was associated with a higher incidence of ECPH.

The incidence of acupuncture-associated ECPH among the subjects included in the study was high. There were significant associations between ECPH and higher frequency of acupuncture as well as thicker diameter of acupuncture needles. Additional studies are required to confirm the findings.

Trial registration number: AMCTR-OOC-17000109.

**Abbreviations:** CI = confidence interval, ECPH = ecchymosis combined with postinflammatory hyperpigmentation, OR = odds ratio, TCM = traditional Chinese medicine, TDP = thermal design power.

**Keywords:** acupuncture, adverse events, ecchymosis, postinflammatory hyperpigmentation

Editor: Dennis Enix.

Guang'anmen Hospital is affiliated with the China Academy of Chinese Medical Sciences. Ethics approval number: 2017-006-KY.

The authors have no conflicts of interest to disclose.

<sup>a</sup> Department of Acupuncture, Guang'anmen Hospital, China Academy of Chinese Medical Sciences, <sup>b</sup> Beijing University of Chinese Medicine, Beijing, <sup>c</sup> Guizhou University of Chinese Medicine, Guiyang, <sup>d</sup> Heilongjiang University of Chinese Medicine, Heilongjiang, <sup>e</sup> Drug Clinical Trial Institution, Guang'anmen Hospital, China Academy of Chinese Medical Sciences, China.

\* Correspondence: Zhishun Liu, Guang'anmen Hospital, China Academy of Chinese Medical Sciences, No. 5, Beixian'ge Street, Xicheng District, Beijing 100053, China (e-mail: liuzhishun@aliyun.com).

Copyright © 2020 the Author(s). Published by Wolters Kluwer Health, Inc. This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial License 4.0 (CCBY-NC), where it is permissible to download, share, remix, transform, and buildup the work provided it is properly cited. The work cannot be used commercially without permission from the journal.

How to cite this article: Zhao Y, Yu J, Liu S, Zhou J, Wang J, Wang Z, Liu Z. Ecchymosis combined with postinflammatory hyperpigmentation associated with acupuncture therapy: An observational study of 167 subjects. *Medicine* 2020;99:4(e18721).

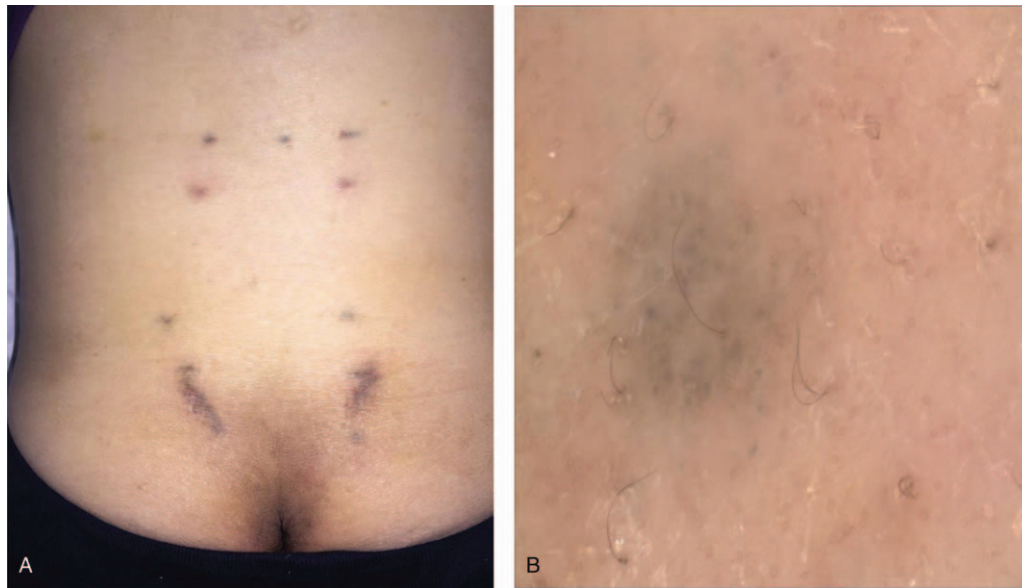
Received: 22 September 2019 / Received in final form: 9 December 2019 / Accepted: 13 December 2019

<http://dx.doi.org/10.1097/MD.00000000000018721>

## 1. Introduction

Acupuncture, as an indispensable part of traditional Chinese medicine (TCM), has been extensively applied in the treatment of numerous diseases for over 2000 years in China. This therapeutic method has been approved by the World Health Organization<sup>[1]</sup> for the treatment of 43 disease types.<sup>[2]</sup> With the increasing popularity of acupuncture across the globe, increasing numbers of diseases are treated with acupuncture. Continual safety assessment is; therefore, necessary.

One of the adverse events associated with acupuncture is ecchymosis combined with postinflammatory hyperpigmentation (ECPH) at the site of acupuncture. ECPH is often observed in patients who have undergone numerous treatment sessions, at the site of needle insertion in the skin (Fig. 1). Compared with hemorrhage or hematoma caused by acupuncture which usually disappears within 1 day or several weeks,<sup>[3,4]</sup> ECPH may persist for 1 year or more which is different from common subcutaneous bruise<sup>[4]</sup> also. The long-time presence of ECPH on exposed skin may trouble some patients very much. Prospective surveys,<sup>[3,5]</sup> cumulative reviews,<sup>[6]</sup> and systematic reviews<sup>[7,8]</sup> have been conducted to explore the adverse effects of acupuncture and associated risk factors. However, previous studies mainly focused



**Figure 1.** The occurrence of ecchymosis combined with postinflammatory hyperpigmentation on the skin (A) and under the electronic dermatoscope (Dermat V2.0.1.0601 DERMOSCOPY-II) (B).

on local hemorrhage or hematoma, infection, nerve injury, lassitude, insomnia, and so on. No ECPH caused by acupuncture was reported. One clinicopathologic review exploring dermatological adverse events associated with acupuncture listed infection risks such as abscess and atypical mycobacterial infection but did not report ECPH.<sup>[9]</sup>

The aim of our study is to investigate the incidence of ECPH at sites where acupuncture has been administered, as well as associated factors.

## 2. Methods

### 2.1. Study design and participants

This study was conducted in the Guang'anmen Hospital, which is affiliated with the China Academy of Chinese Medical Sciences. A 1-page questionnaire that included 14 items was used to collect patient data. The first draft of the questionnaire was designed according to Clinical Dermatology of China<sup>[10]</sup> and reviewed by 2 acupuncture specialists and 1 dermatology specialist. The formal version of the questionnaire was in adherence with their opinions and epidemiologic standards.

During the period from March 7, 2017 to March 6, 2018, subjects were recruited from 3 acupuncture clinics at Guang'anmen Hospital. All patients included in the study met the following criteria:

- (1) more than 10 sessions of continuous acupuncture therapy (not less than 1 session per week) for treatment of the same disease, using the same method of acupuncture treatment;
- (2) normal cognitive and language functions. All participants provided their signed informed consent for participation in the study.

Bodily locations at which acupuncture was received were classified as: head/face, chest, abdomen, back, sacrum, upper limb, or lower limb. Bodily locations where acupuncture was administered and sites with evidence of ECPH were identified and recorded at the end of each visit, from the 10th session of acupuncture to the end of treatment.

The demographic characteristics investigated included age, sex, and health status (history of diabetes, history of immune dysfunction). Dermatologic features were investigated with questions pertaining to history of allergic contact dermatitis, allergy to metal, and/or keloid. For each patient, the following information was collected: type of acupuncture (manual acupuncture or electroacupuncture), frequency of acupuncture (1–7 sessions per week), bodily location of acupuncture (head/face, chest, abdomen, back, sacrum, upper limb, lower limb), diameter of acupuncture needles (0.25 mm, 0.30 mm, or 0.35 mm), and total number of acupuncture sessions (20–29, 30–39, 40–49, 50–59, 60–69, 70–79, 80–89, ≥90 sessions). The potential risk factors investigated included method of disinfection (alcohol, iodophor) and exposure of the acupuncture site to a thermal design power (TDP) lamp.

### 2.2. Data collection on-site

We screened for patients who had received more than 10 sessions of acupuncture treatment. Two postgraduate students were trained to collect questionnaire data. Interviewers recorded demographic characteristics such as age, sex, health status (history of diabetes, history of immune dysfunction), dermatologic features (history of allergic contact dermatitis, keloid, or allergy to metal). Acupuncture-related factors that were recorded included type and frequency of acupuncture, bodily location to which acupuncture treatment was administered, acupuncture needle diameter, total number of acupuncture sessions. The potential risk factors included method of disinfection, and exposure to a TDP lamp. Follow-up visits were conducted every 10 sessions of acupuncture treatment, until ECPH was observed or the patient had completed the whole treatment. A spot check was conducted to evaluate the quality of completed questionnaires.

### 2.3. Statistical analysis

The original data was logged into an electronic system by 2 postgraduate students, working independently. This information

was cross-verified with the original paper record. The information collected by questionnaire was used to determine the incidence of ECPH. We used the Chi-square test to evaluate associations between demographic information, dermatologic features, acupuncture-related factors, and other factors potentially associated with ECPH. Cox proportional hazards regression models were used to determine the hazard ratios (HRs) of ECPH with acupuncture frequency or acupuncture needle diameter, using number of acupuncture sessions completed as the time variable.

The statistical significance of results was determined using 2-tailed  $\alpha$ -level of 0.05. All statistical analyses were performed with IBM SPSS software, V.20 Statistics.

### 2.4. Patient and public involvement

Subjects were recruited from 3 acupuncture clinics, first, we asked patients from the 3 clinics whether they would like to participate in this study, and then if they met the 2 criteria stated above, they would be involved. Patients were not involved in the recruitment and conduct of the study. The results would be disseminated by phone or e-mail to study participants. The development of the research and outcome measures would be informed to the patients when they were involved face to face.

## 3. Results

The study ultimately enrolled 186 subjects. Nineteen subjects were excluded from analysis because of incomplete questionnaires or loss to follow-up. After exclusion of invalid data, 167 subjects were included in the final analysis. Among these 167 subjects, acupuncture was administered at 1 or several bodily locations. For each subject, 1 bodily location met 1 questionnaire. Finally, we collected 326 completed questionnaires, including 326 bodily locations of ECPH. The total incidence of ECPH in all subjects who accepted >10 sessions of acupuncture was 70.06%

(117/167); the total incidence of ECPH among all bodily locations that received acupuncture was 67.79% (221/326).

### 3.1. Demographic characteristics

Among the 167 subjects included, 90 were women, and 77 were men. The median age of subjects was 57 years (interquartile range, 38–68). The incidence of ECPH was similar in women and men (odds ratio [OR], 1.006; 95% confidence interval [CI]: 0.518–1.955) and in subjects with versus without immune dysfunction (OR, 0.319; 95% CI, 0.082–1.241). The incidence of ECPH was decreased in patients with diabetes, compared to patients without diabetes (OR, 0.368; 95% CI: 0.148–0.917) (Table 1).

### 3.2. Dermatologic features

Among all subjects, there were no associations between ECPH and allergic contact dermatitis, allergy to metal, or keloid, with ORs of 0.574 (95% CI: 0.205–1.606), 0.847 (95% CI: 0.203–3.529), and 0.407 (95% CI: 0.098–1.697), respectively (Table 1).

### 3.3. Acupuncture-related factors

There was no significant association between type of acupuncture and incidence of ECPH (OR, 1.065; 95% CI: 0.594–1.911). Significant associations were found between ECPH and the following acupuncture-related factors: frequency of acupuncture ( $P < .05$ ), bodily location of acupuncture ( $P < .05$ ), diameter of acupuncture needle ( $P < .05$ ), and total number of acupuncture sessions ( $P < .05$ ) (Table 2).

### 3.4. Other related factors

In all cases, skin was disinfected with a solution of 75% alcohol. There was no association between ECPH and exposure to a TDP lamp (OR, 0.635; 95% CI, 0.355–1.136) (Table 2).

**Table 1**  
Demographic and clinical data in subjects with and without ecchymosis combined with postinflammatory hyperpigmentation.

Variables	Ecchymosis combined with postinflammatory hyperpigmentation		$\chi^2$	OR, 95% CI	P
	No	Yes			
Demographic characteristics					
Gender					
Female	27 (30.0)	63 (70.0)	0.000	1.006 (0.518–1.955)	.985
Male	23 (29.9)	54 (70.1)			
Diabetes					
No	39 (26.9)	106 (73.1)	4.515	0.368 (0.148–0.917)	.034
Yes	11 (50.0)	11 (50.0)			
Immune system disease					
No	45 (28.5)	113 (71.5)	2.703	0.319 (0.082–1.241)	.100
Yes	5 (55.6)	4 (44.4)			
Dermatologic feature					
Allergic contact dermatitis					
No	43 (28.7)	107 (71.3)	1.082	0.574 (0.205–1.606)	.298
Yes	7 (41.2)	10 (58.8)			
Allergic to metal					
No	47 (29.7)	111 (70.3)	0.051	0.847 (0.203–3.529)	.821
Yes	3 (33.3)	6 (66.7)			
Keloid					
No	46 (28.9)	113 (71.1)	1.482	0.407 (0.098–1.697)	.224
Yes	4 (50.0)	4 (50.0)			

CI=confidence interval, OR=odds ratio.

**Table 2**  
**Acupuncture-related and potential risk factors in subjects with and without ecchymosis combined with postinflammatory hyperpigmentation.**

Variables	Ecchymosis combined with postinflammatory hyperpigmentation		$\chi^2$	OR, 95% CI	P
	No	Yes			
Acupuncture-related factors					
Type of acupuncture					
Electro-acupuncture	21 (33.3)	42 (66.7)	0.450	1.065 (0.594–1.911)	.832
Manual acupuncture	84 (31.9)	179 (68.1)			
Frequency of acupuncture, session (s) per wk					
1	7 (100.0)	0 (0.0)	163.116	0.368 (0.148–0.917)	<.050
2	11 (61.1)	7 (38.9)			
3	49 (77.8)	14 (22.2)			
4	10 (66.7)	5 (33.3)			
5	17 (43.6)	22 (56.4)			
6	11 (6.0)	173 (94.0)			
7	0 (0.0)	0 (0.0)			
Diameter of acupuncture needles, mm					
0.25	15 (7.8)	178 (92.2)	228.407		<.050
0.30	87 (91.6)	8 (8.4)			
0.35	3 (7.9)	35 (92.1)			
Total acupuncture sessions, sessions					
11	1 (100.0)	0 (0.0)	108.269		<.050
20–29	30 (14.4)	178 (85.6)			
30–39	18 (43.9)	23 (56.1)			
40–49	19 (73.1)	7 (26.9)			
50–59	3 (37.5)	5 (62.5)			
60–69	8 (61.5)	5 (38.5)			
70–79	8 (80.0)	2 (20.0)			
80–89	5 (83.3)	1 (16.7)			
≥90	13 (100.0)	0 (0.0)			
Bodily location of acupuncture					
Head/face	30 (32.6)	62 (67.4)	27.653	0.319 (0.082–1.241)	<.050
Chest	1 (11.1)	8 (88.9)			
Abdomen	14 (73.7)	5 (26.3)			
Back	10 (62.5)	6 (37.5)			
Sacrum	8 (17.8)	37 (82.2)			
Upper limbs	24 (30)	56 (70)			
Lower limbs	18 (27.7)	47 (72.3)			
Potential risk factors					
Exposure of the acupuncture site to a thermal design power lamp					
No	81 (30.3)	186 (69.7)	2.297	0.635 (0.355–1.136)	.130
Yes	24 (40.7)	8 (42.1)			

CI=confidence interval, OR=odds ratio.

Based on the results collected, which were interpreted in the context of our clinical experience, we decided to perform survival analysis using the following factors: frequency of acupuncture, acupuncture needle diameter, and total number of acupuncture sessions. For the Cox proportional hazards model, we chose acupuncture sessions as the time variable. The results showed no clear association between ECPH and low-frequency acupuncture ( $\leq 2$  sessions per week) but showed a clear association between ECPH and high-frequency acupuncture ( $> 2$  sessions per week). Higher frequency of acupuncture was associated with higher incidence of ECPH in subjects treated with more than 2 sessions per week of acupuncture. The hazard ratio for ECPH among patients who received 3 sessions of acupuncture per week, compared with those who received 6 sessions per week, was 0.082 (95% CI, 0.044–0.152;  $P = .000$ ). The hazard ratio for ECPH among patients who received 4 sessions of acupuncture per week, compared with those who received 6 sessions per week, was 0.193 (95% CI, 0.078–0.480;  $P = .000$ ). The hazard ratio for

ECPH among patients who received 5 sessions of acupuncture per week, compared with those who received 6 sessions per week, was 0.226 (95% CI, 0.134–0.381;  $P = .000$ ). Similar results were obtained after adjustment for acupuncture needle diameter. For 3 sessions per week, compared with 6 sessions per week, these values were: HR, 0.170; 95% CI: 0.066–0.437;  $P = .000$ . For 4 sessions per week, compared with 6 sessions per week, these values were: HR, 0.222; 95% CI: 0.058–0.858;  $P = .029$ . For 5 sessions per week, compared with 6 sessions per week, these values were: HR, 0.294; 95% CI: 0.096–0.900;  $P = .032$  (Table 3 and Fig. 2).

Acupuncture needle diameter of 0.25 mm was associated with the highest incidence of ECPH (HR, 1.767; 95% CI: 1.193–2.617;  $P = .005$ ); acupuncture needle diameter of 0.30 mm was associated with the lowest incidence of ECPH (HR, 0.064; 95% CI: 0.029–0.139;  $P = .000$ ). However, after adjustment for frequency of acupuncture, diameter of 0.25 mm was excluded from analysis ( $P = .342$ ). The results presented indicate that

**Table 3**  
**Survival analysis of ecchymosis combined with postinflammatory hyperpigmentation (ECPH) in acupuncture frequency and needle diameter.**

Acupuncture related factors	No.	ECPH	Session of ECPH occurrence, median (IQR)	Univariate hazard ratio (95% CI), P	Multivariate hazard ratio (95% CI), P
Frequency of acupuncture, session(s) per wk					
1	7	0	–	0.000, .947	0.000, .953*
2	18	7	30 (30.0–50.0)	0.140 (0.062–0.314), .000	0.433 (0.122–1.539), .196*
3	63	14	40 (30.0–52.5)	0.082 (0.044–0.152), .000	0.170 (0.066–0.437), .000*
4	15	5	30 (20.0–55.0)	0.193 (0.078–0.480), .000	0.222 (0.058–0.858), .029*
5	39	22	25 (20.0–32.5)	0.226 (0.134–0.381), .000	0.294 (0.096–0.900), .032*
6	184	173	20 (20.0–20.0)	1	1
Diameter of acupuncture, mm					
0.25	193	178	20 (20.0–20.0)	1.767 (1.193–2.617), .005	0.609 (0.219–1.695), .342†
0.30	95	8	40 (30.0–60.0)	0.064 (0.029–0.139), .000	0.058 (0.025–0.132), .000†
0.35	38	35	30 (20.0–40.0)	1	1

CI=confidence interval, ECPH=ecchymosis combined with postinflammatory hyperpigmentation.

\* Adjusted for diameter of acupuncture.

† Adjusted for frequency of acupuncture.

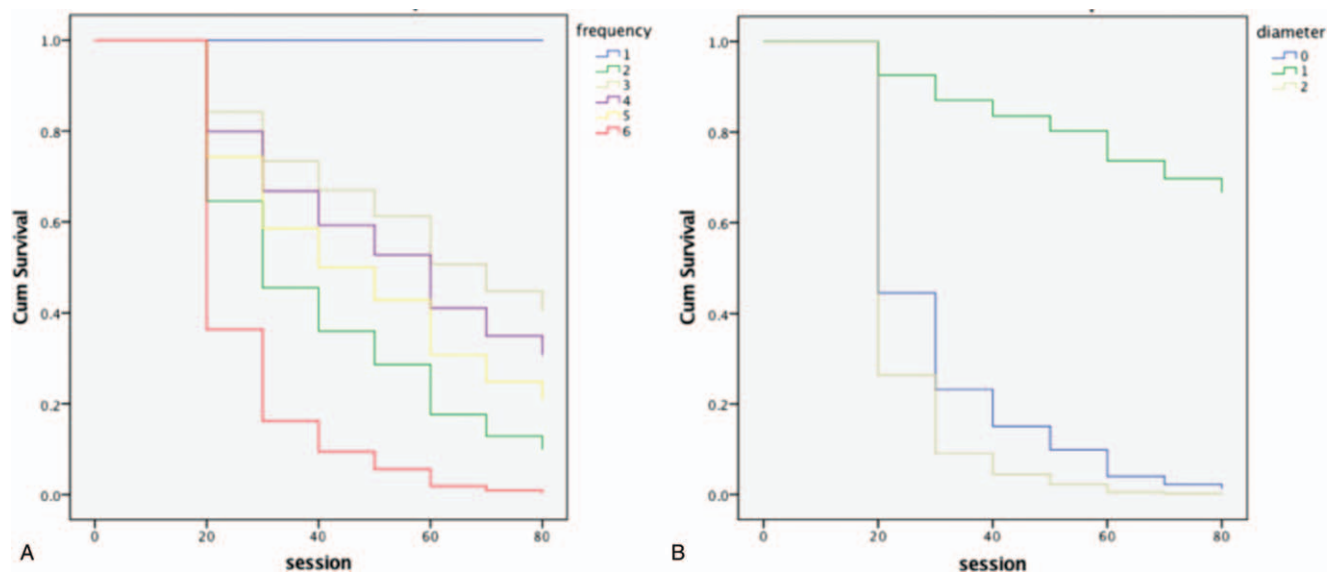
increased acupuncture needle diameter (0.35 mm vs 0.30 mm) was associated with increased incidence of ECPH. When compared with 0.35 mm, the HR of ECPH for 0.30-mm diameter was 0.058 (95% CI: 0.025–0.132; P=.000) (Table 3 and Fig. 2).

**4. Discussion**

TCM, practiced in China for over 5000 years, is a practice based on experience and a conception of unity between body and spirit. As an important component of TCM, acupuncture has recently attracted significant attention among the medical community.<sup>[11]</sup> In 2010, Chinese acupuncture was officially listed as a representation of “human intangible cultural heritage” by the

United Nations Educational, Scientific, and Cultural Organization.<sup>[12]</sup> After years of development, acupuncture has become an indispensable method for complementary and alternative medicine in countries such as the United States,<sup>[12]</sup> Switzerland,<sup>[13]</sup> Germany,<sup>[14]</sup> Australia,<sup>[15]</sup> and Japan.<sup>[16]</sup> Despite the use of acupuncture across the globe, surveys on adverse events are relatively rare. Although some studies have reported adverse effects of acupuncture,<sup>[3,5,9]</sup> no previous study has investigated ECPH, which is a common dermatologic occurrence after acupuncture.

This study initially included 186 subjects. However, after application of the exclusion criteria, 167 subjects and 326 bodily locations were ultimately included. Among these 167 subjects



**Figure 2.** (A) Differences pertaining to incidence of ECPH for frequency of acupuncture by Cox proportional hazards regression models. (X-axis presents total sessions of acupuncture. Y-axis presents incidence of ECPH. 1.0 means no ECPH and 0.0 means ECPH. 1 presents frequency of acupuncture for 1 time per wk. 2 presents frequency of acupuncture for 2 times per wk. 3 presents frequency of acupuncture for 3 times per wk. 4 presents frequency of acupuncture for 4 times per wk. 5 presents frequency of acupuncture for 5 times per wk. 6 presents frequency of acupuncture for 6 times per wk). (B) Differences pertaining to incidence of ECPH for diameter of acupuncture needles by Cox proportional hazards regression models. (X-axis presents total sessions of acupuncture. Y-axis presents incidence of ECPH. 1.0 means no ECPH and 0.0 means ECPH. 0 presents 0.25 mm. 1 presents 0.30 mm. 2 presents 0.35 mm). ECPH = ecchymosis combined with postinflammatory hyperpigmentation.

and 326 bodily locations, ECPH occurred in 117 subjects (70.06%, 117/167) and 221 bodily locations (67.79%, 221/326). Compared with previous studies, ECPH presented a higher incidence than hemorrhage (32%) and hematoma (28%) in 1 prospective survey,<sup>[3]</sup> or subcutaneous hematoma (43.24%) and subcutaneous bruise (37.84%) in a review.<sup>[4]</sup> Four related factors were found to be associated with ECPH ( $P < .05$ ): frequency of acupuncture, acupuncture needle diameter, total number of acupuncture sessions, and bodily location where acupuncture was administered. Higher frequency of acupuncture was associated with increased incidence of ECPH in subjects treated with  $>2$  sessions per week of acupuncture. Thicker acupuncture needle diameter was also associated with a higher incidence of ECPH.

One clinicopathologic review<sup>[9]</sup> reported adverse events associated with acupuncture and investigated associated risk factors. While that study included 25 patients, ours included 167 subjects (acupuncture needles inserted at 326 bodily locations inserted). Our study thus included a larger sample size and was more representative. In addition, our study focused on 2 common types of acupuncture (electro-acupuncture and manual acupuncture), while the review included rare types of acupuncture, such as bee venom acupuncture, herbal acupuncture, and embedding acupuncture.<sup>[9]</sup> The use of chemical substances is required for bee venom acupuncture and may lead to infectious skin disease. This risk factor is avoided with the use of disposable aseptic steel acupuncture needles in the settings of electro-acupuncture and manual acupuncture. The results of our study are therefore more applicable to the practice of acupuncture.

In terms of related risk factors, we found that higher frequency of acupuncture was associated with higher incidence of ECPH in subjects treated with more than 2 sessions per week of acupuncture. Ecchymosis is a common adverse effect of acupuncture.<sup>[8]</sup> Postinflammatory hyperpigmentation can also occur at sites where acupuncture has been administered after repeated insertion of acupuncture needles. Postinflammatory hyperpigmentation occurs after acute or chronic inflammation of the skin.<sup>[10]</sup> Ecchymosis or postinflammatory hyperpigmentation usually disappears after several weeks.<sup>[8,10]</sup> However, based on our clinical observations and reports from outpatients, long-term, repeated insertion of acupuncture needles may result in ECPH that persists for 1 year or more. The presence of ECPH on exposed skin may be unacceptable to some patients. It is therefore extremely important to identify related risk factors.

The results of univariate analysis with Cox proportional hazards regression models indicated that use of 0.25-mm-diameter acupuncture needles was most likely to lead to ECPH (HR:1.767; 95% CI: 1.193–2.617). The statistical analysis above also indicated that subjects who received treatments with 0.25-mm-diameter needles also received acupuncture most frequently (6 sessions per week). After adjustment for the frequency of acupuncture in multivariate analysis, 0.25-mm diameter of acupuncture needles was excluded, and 0.35-mm-diameter needles were found to increase incidence of ECPH, compared with needles of 0.30-mm diameter. 0.25-mm-diameter needles with other frequency ( $<6$  sessions per week) almost were not observed because of the shortage of subjects.

Though there was a significant association between ECPH and diabetes ( $P = .034$ ), we could not draw a clear conclusion about their association because of the low prevalence of diabetes in this study (13.17%, 22/167).

According to the Chi-square test, bodily location at which acupuncture was administered had a significant association with ECPH ( $P < .05$ ). Among the 326 bodily locations, the number of bodily locations at which acupuncture needles were inserted were 9 in the chest, 45 in the sacrum, 65 in the lower limbs, 80 in the upper limbs, 92 in head/face, 16 in the back, and 19 in the abdomen. The incidence of ECPH was highest in chest (8/9, 88.9%), followed by sacrum (37/45, 82.2%), lower limbs (47/65, 72.3%), upper limbs (56/80, 70%), head/face (62/92, 67.4%), back (6/16, 37.5), and abdomen (5/19, 26.3%). These data were not analyzed with Cox proportional hazards regression models because the sample sizes of some groups were too small.

#### 4.1. Strengths and limitations

To our knowledge, this is the first study about dermatological adverse events associated with acupuncture to systematically investigate the incidence of ECPH during normal acupuncture therapy. This study not only explored the associations between ECPH and acupuncture-related factors but also investigated associations between participant characteristics and the incidence of ECPH. All interviewers underwent strict training to guarantee the quality of the data collected. Multivariate analysis was conducted after univariate analysis to determine the effect of confounding factors. The results were used to identify risk factors related to ECPH.

Because of the shortage of staff, this study was only conducted in 1 hospital in Beijing. Regional differences were thus not taken into consideration. This study did not investigate needling depth or differences among acupuncturists, which may have affected the incidence of ECPH. The minimum total acupuncture sessions were 11 sessions and the maximum of that were more than 90 sessions. Additional studies including larger sample populations, longer observation and comprehensive questionnaires are required.

## 5. Conclusion

The incidence of ECPH associated with acupuncture was high. There were significant associations between ECPH and higher frequency of acupuncture, as well as thicker acupuncture needle diameter. Additional studies are required to confirm the findings.

## Acknowledgments

We appreciate the great help of Dr Junzhi Wang, dermatologist from First Affiliated Hospital of Heilongjiang University of Chinese Medicine, for his professional advice in designing the original questionnaire.

## Author contributions

**Conceptualization:** Yuwei Zhao, Zhishun Liu.

**Data Curation:** Yuwei Zhao, Jinna Yu.

**Formal Analysis:** Yuwei Zhao, Jinna Yu, Jing Wang.

**Investigation:** Yuwei Zhao, Sixing Liu, Jing Zhou, Zhaobo Wang.

**Methodology:** Yuwei Zhao, Jinna Yu, Zhishun Liu.

**Project Administration:** Sixing Liu, Jing Zhou, Zhaobo Wang.

**Resources:** Yuwei Zhao, Jinna Yu

**Software:** Yuwei Zhao, Jinna Yu, Jing Wang.

**Supervision:** Zhishun Liu.

**Validation:** Zhishun Liu.

**Writing – original draft preparation:** YuweiZhao, Jinna Yu.  
**Writing – review and editing:** Yuwei Zhao, Jinna Yu, Zhishun Liu.  
 Zhishun Liu orcid: 0000-0001-7570-8917.

## References

- [1] Altshuler LH, Maher JH. Acupuncture: a physicians primer, part II. *J Okla State Med Assoc* 2003;96:13–9.
- [2] The WHO, recommends 43 diseases of acupuncture. *Clin J Tradit Chin Med* 2012;24:519.
- [3] Park JE, Lee MS, Choi JY, et al. Adverse events associated with acupuncture: a prospective survey. *J Altern Complement Med* 2010;16:959–63.
- [4] Zhao L, Zhang FW, Li Y, et al. Analysis and common on the occurrence of adverse events in 1968 patients after acupuncture. Chinese Acupuncture Society Evidence-Based Acupuncture Committee, Chinese Acupuncture Society Committee on Encephalopathy. 2010 Proceedings of the Chinese Academy of Acupuncture and Moxibustion Professional Committee and Evidence-Based Acupuncture Committee of the Chinese Acupuncture Association. Evidence-Based Acupuncture Professional Committee of Chinese Acupuncture Society, Encephalopathy Professional Committee of Chinese Acupuncture Society; 2010:8.
- [5] Macpherson H, Scullion A, Thomas KJ, et al. Patient reports of adverse event associated with acupuncture treatment: a prospective national survey. *Qual Saf Health Care* 2004;13:349–55.
- [6] White A. A cumulative review of the range and incidence of significant adverse events associated with acupuncture. *Acupunct Med* 2004;22:122–33.
- [7] Wu J, Hu Y, Zhu Y, et al. Systematic review of adverse effects: a further step towards modernization of acupuncture in China. *Evid Based Complement Alternat Med* 2005;2005:432467.
- [8] Ernst E, White A. Prospective studies of the safety of acupuncture: a systematic review. *Am J Med* 2001;110:481–5.
- [9] Park SM, Kim WJ, Mun JH, et al. Adverse events associated with acupuncture: a clinicopathologic review. *Int J Dermatol* 2016;55:757–63.
- [10] Zhao B. *Clinical Dermatology of China*. 4th ed. Nanjing, Jiangsu: Jiangsu Science and Technology Press; 2010.
- [11] Fu JY, Zhang X, Zhao YH, et al. The general situation of the global development of Chinese medicine research in the last 30 years. *Asia Pac Tradit Med* 2013;9:9–11.
- [12] Liu XY, Zhao HL, Wu Y, et al. The current development and Prospect of Chinese acupuncture and moxibustion in the United States. *World Chin Med* 2017;12:700–3.
- [13] Li SL. The development of Chinese acupuncture and moxibustion in Switzerland. *Chin Acupunct* 2004;4:63–5.
- [14] Sun ZH. The thinking of the development of acupuncture and moxibustion in Switzerland and Germany. *Jiangsu J Tradit Chin Med* 2011;43:72–3.
- [15] R X, L FX. Development and status of acupuncture and moxibustion in Australia. *World Chin Med* 2016;11:2807–12.
- [16] Xu RY, Li HY, Li JD. A survey of the development of acupuncture and moxibustion in Japan. *World J Integr Tradit Western Med* 2016;11:426–8.