

OS06.05

**Clinical Evidence of Chinese Herbal Medicine for Treatment of Idiopathic Sudden Sensorineural Hearing Loss from Chinese Literature**



Chun-Xiang Su<sup>1</sup>, Zhong Sun<sup>2</sup>, Shu-Jin Yue<sup>2</sup>, Yu-Fang Hao<sup>2</sup>, Jian-Ping Liu<sup>1,\*</sup>

<sup>1</sup>Center for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine, Chaoyang District, Beijing 100029, China

<sup>2</sup>School of Nursing, Beijing University of Chinese Medicine, Chaoyang District, Beijing 100102, China

**Purpose:** To provide a comprehensive summary of all clinical evidence on Chinese herbal medicine (CHM) for idiopathic sudden sensorineural hearing loss (ISSHL) published in Chinese literature.

**Methods:** We systematically searched randomized clinical trials (RCTs), clinical controlled trials (CCTs), case series (CSs) and case reports (CRs) which reported CHM for ISSHL through four main Chinese electronic databases from their inception to March 2014. We bibliometrically analyzed the studies and assessed the methodological quality of RCTs using the Cochrane risk of bias tool.

**Results:** A total of 299 clinical studies with involving 22,237 participants were identified including 150 RCTs, 42 CCTs, 80 CSs and 27 CRs. The number of publications increased obviously per year from 1995, with the peak in 2011. Among 145 different herbal formulae tested, the most popular prescribed herbal formulae were Longdan Xiegan decoction and Tongqiao Huoxue decoction, and the top three frequently used Chinese herbs were Rhizoma Chuanxiong, Radix Bupleuri and Radix Puerariae Lobatae. The most frequently reported outcome was improvement of hearing in 286 (95.7%), followed by improvement of tinnitus (139, 46.5%), improvement of dizziness (99, 33.1%). Among the 150 RCTs, randomization methods were described in only 12 trials (8.0%). No trial reported allocation concealment and only four mentioned blinding. Among 146 RCTs (97.3%) and 37 CCTs (88.1%) reporting improvement of hearing as the outcome measurement, all showed significant difference favoring CHM. Of 16 trials reporting adverse events, only five trials reported mild adverse events related to CHM and the remaining stated that none had occurred.

**Conclusion:** The quantity of clinical research on CHM for ISSHL is substantial, but methodological quality of RCTs is generally suboptimal. Future clinical studies would need to report structurally and based on the CONSORT and TREND Statements. Quality of life, adverse events, depression and anxiety should be addressed as outcome measures.

**Contact:** Chun-Xiang Su, [susu18182004@126.com](mailto:susu18182004@126.com)

**Corresponding Author:** Jian-Ping Liu (Center for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine, Chaoyang District, Beijing 100029, China), [jianping.l@hotmail.com](mailto:jianping.l@hotmail.com)

<http://dx.doi.org/10.1016/j.imr.2015.04.312>

OS06.06

**Empirical evidence for outcome reporting bias in randomized clinical trials of acupuncture: comparison of registered records and subsequent publications**



Chun-Xiang Su<sup>1</sup>, Mei Han<sup>1</sup>, Jun Ren<sup>1</sup>, Wen-Yuan Li<sup>1</sup>, Shu-Jin Yue<sup>2</sup>, Yu-Fang Hao<sup>2</sup>, Jian-Ping Liu<sup>1,\*</sup>

<sup>1</sup>Center for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine, Chaoyang District, Beijing 100029, China

<sup>2</sup>School of Nursing, Beijing University of Chinese Medicine, Chaoyang District, Beijing 100102, China

**Purpose:** To evaluate the consistency between the registered records and subsequent publications regarding outcomes and other data, and to determine whether outcome reporting bias favored significant primary outcomes.

**Methods:** We systematically searched 15 registries from their inception to January 2014 to identify randomized clinical trials (RCTs) on acupuncture that the status was listed as 'completed'. The subsequent publications were retrieved by searching PubMed and three Chinese databases. Basic characteristics and the registration information were extracted from registered records and publications. We performed comparisons regarding primary outcomes and other data between the registered records and publications to assess the consistency and selective outcome reporting.

**Results:** Eighty-eight trials on acupuncture with 96 publications were identified. Only 19.3% (17/88) were registered before the start of the trial. The trial registered number was not reported in 36 publications (25.9%). A comparison of registered and published primary outcomes could be conducted in 71 publications (74.0%), and the inconsistency of the primary outcomes was identified in 44.4% (32 of 71), mainly involving in registered primary outcome omitted in the publications (22/32, 68.75%), followed by registered primary outcome reported as secondary outcome in the publications (15/32, 46.9%). 71.4% (15 of 21) had a discrepancy that favored statistically significant primary outcomes while 28.6% (6 of 21) favored nonsignificant primary outcomes. Furthermore, the other inconsistencies between the registry records and publications involved in inclusion criteria (54.7%), exclusion criteria (47.9%), and control (22.9%).

**Conclusion:** We find that the proportion of retrospective registration for RCTs on acupuncture is high, selective outcome reporting is prevalent, and the change of primary outcomes intends to favor results with statistical significance. These discrepancies in outcome reporting may lead to biased and misleading results of RCTs on acupuncture. To ensure publication of reliable and unbiased results, further promotion and implementation of trial registration is still needed.

**Contact:** Chun-Xiang Su, [susu18182004@126.com](mailto:susu18182004@126.com)