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Xingnao Kaiqiao needling method for acute ischemic stroke: a meta-analysis of safety and efficacy

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Abstract

OBJECTIVE: To evaluate the effectiveness and safety of the *Xingnao Kaiqiao* needling method for treating acute ischemic stroke.
DATA SOURCES: We retrieved relevant randomized controlled trials involving *Xingnao Kaiqiao* acupuncture for treatment of acute ischemic stroke. The China National Knowledge Infrastructure, Weipu Information Resources System, Wanfang Medical Data System, Chinese Biomedical Literature Database, Cochrane Library, and PubMed were searched from June 2006 to March 2016.
DATA SELECTION: We analyzed randomized and semi-randomized clinical controlled trials that compared *Xingnao Kaiqiao* acupuncture with various control treatments, such as conventional drugs or other acupuncture therapies, for treatment of acute ischemic stroke. The quality of articles was evaluated according to the Cochrane Handbook for Systematic Reviews of Interventions (Version 5.1), and the study was carried out using Cochrane system assessment methods. RevMan 5.2 was used for the meta-analysis of the included studies.
OUTCOME MEASURES: The mortality rate, disability rate, activities of daily living (Barthel Index), and clinical efficacy were observed.
RESULTS: Twelve studies met the inclusion criteria for this review. The meta-analysis showed that between *Xingnao Kaiqiao* acupuncture and the control treatment, *Xingnao Kaiqiao* acupuncture reduced the disability rate [risk ratio (*RR*) = 0.51, 95% confidence interval (*CI*) = 0.27–0.98, $z = 2.03$, $P < 0.05$], elevated the activities of daily living (weighted mean difference = 12.23, 95% *CI*: 3.66–20.08, $z = 2.80$, $P < 0.005$), and had greater clinical efficacy (*RR* = 1.61, 95% *CI*: 1.23–2.09, $z = 3.53$, $P < 0.0004$). However, there was no significant difference in mortality rate (*RR* = 0.61, 95% *CI*: 0.15–2.45, $z = 0.70$, $P > 0.05$).
CONCLUSION: The *Xingnao Kaiqiao* needling method is effective and safe for acute ischemic stroke. However, there was selective bias in this study, and the likelihood of measurement bias is high. Thus, more high-quality randomized controlled trials are needed to provide reliable evidence of the efficacy and safety of *Xingnao Kaiqiao* acupuncture in the treatment of acute ischemic stroke.

Key Words: *nerve regeneration; Xingnao Kaiqiao needling method; acute ischemic stroke; meta-analysis; systematic review; activities of daily living; Barthel index; mortality; disability rate; clinical efficacy; neural regeneration*

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Introduction

Stroke is a leading cause of death and long-term disability in adults worldwide (Goldstein et al., 2011; Cheng et al., 2013). More than 80% of strokes originate from ischemic damage to the brain caused by an acute reduction in the blood supply, causing neurological deficits and functional impairment (Przybylowski et al., 2014). The acute and subacute stages are the most important periods in the course of stroke rehabilitation (Lackland et al., 2014).

Acupuncture has been used to treat stroke in China for more than 1,000 years; it has also been recommended by the World Health Organization (2002). Acupuncture has been widely used to improve motor, sensation, language, and other neurological functions in patients with stroke (Ramee and White, 2014). The *Xingnao Kaiqiao* (XNKQ) needling method is a well-recognized element of acupuncture in China. The XNKQ needling method is based on long-term clinical experiments and was developed in 1972 by Professor Xuemin Shi, an academician of the Chinese Academy of Engineering (Shi, 1998).

Clinical experience and some animal studies have indicated that the XNKQ needling method is significantly effective and safe in stroke management, especially in the treatment of acute ischemic stroke (Wen et al., 2005; Yang et al., 2008; Sun et al., 2009; Shen et al., 2012; Chen and Ni, 2013). Manipulation of the XNKQ needling method varies in accordance with the patient's condition. In general, the points *Neiguan* (PC6), *Renzhong* (GV26), *Sanyinjiao* (SP6), *Jiquan* (HT1), *Weizhong* (BL40), and *Chize* (LU5) are involved in therapeutic regimen; *Fengchi* (GB20), *Yifeng* (TE17), and *Wangu* (GB12) are used for dysphagia; *Hegu* (LI4) is applied in patients with finger dysfunction; *Qiuxu* (GB40) and *Zhao-*

hai (KI6) are used for pes adductus; and *Lianquan* (CV23) and blood-letting therapy on *Jinjin* (Ex-HN12) and *Yuye* (Ex-HN13) are used for slurred speech. The XNKQ needling method is now a widely accepted intervention for the treatment of acute ischemic stroke; however, comprehensive evaluations and systematic reviews of its effectiveness and safety are lacking. No systematic review of this subject has yet been performed. For this reason, we carried out the present systematic review to critically assess evidence from randomized clinical trials (RCTs) of the XNKQ needling method performed to improve symptoms of acute ischemic stroke.

Methods

Data sources

This paper was prepared in accordance with the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA guidelines).

The following digital databases were searched for relevant studies published from June 2006 to March 2016: the Cochrane Central Register of Controlled Trials (up to the Cochrane Library Issue 03, 2016), MEDLINE, CINAHL, AMED, Embase, and four Chinese databases: China National Knowledge Infrastructure, WEIPU Information Resources System, Wanfang Medical Data System, and Chinese Biomedical Literature Database. In addition, the following journals were searched by manual retrieval: *Chinese Acupuncture and Moxibustion*, *Acupuncture Research*, *Journal of Traditional Chinese Medicine, Journal of Clinical Acupuncture and Moxibustion*, *Shanghai Journal of Acupuncture and Moxibustion*, *Journal of New Chinese Medicine*, *Tianjin Journal of Traditional Chinese Medicine*, *Shanghai Journal of Traditional Chinese Medicine*,*Jiangsu Journal of Traditional Chinese Medicine*, *Liaoning Journal of Traditional Chinese Medicine*, and *Zhejiang Journal of Traditional Chinese Medicine*.

The following terms were used for retrieval of English literature: "*Xingnao Kaiqiao*," "stroke," "ischemic stroke," "cerebrovascular accident," "apoplexy," "ischemia apoplexy," "cerebral infarction," "cerebral embolism," "cerebral thrombosis," and "transient ischemic attack." The following terms were used for retrieval of Chinese literature: "*Xingnao Kaiqiao* needling method" and "stroke" (apoplexy, cerebrovascular accidents, ischemic stroke, cerebral infarction, cerebral thrombosis, transient ischemic attack, and cerebral embolism).

Study selection

All clinical RCTs of the XNKQ needling method for acute ischemic stroke were considered. The studies were eligible for inclusion if they met the following inclusion criteria: (1) The diagnosis of stroke met the diagnostic criteria of the World Health Organization (No authors listed, 1989) or National Conference of Cerebrovascular Disease (China) (Chinese Neuroscience Society, 1997). (2) The study was performed irrespective of sex or age but was an RCT in patients with an onset of acute ischemic stroke within 2 weeks (Writing Group of Guidelines for Diagnosis and Treatment of Acute Ischemic Stroke, Cerebrovascular Disease Group, Neurological Section, Chinese Medical Association, 2011). (3) The treatment group underwent the XNKQ needling method alone or combined with other treatment methods, while the control group underwent traditional acupuncture alone or with other treatment methods excluding the XNKQ needling method. (4) Mortality, disability, safety and health, economic indicators, activities of daily living (Barthel index), and clinical efficacy were evaluated. Studies were excluded if traditional acupuncture or other treatments were used in addition to the XNKQ needling method in the treatment group but not in the control group.

Data extraction and assessment of risk of bias

According to the Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1 (Higgins and Green, 2013), the selected articles were evaluated with respect to the following six criteria: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other issues. Each criterion was judged using one of three answers: "yes," "no," or "unclear." "Yes" indicated a low risk of bias, "no" indicated a high risk of bias, and "unclear" indicated that insufficient information was available for this judgment.

Two independent reviewers screened the titles and abstracts of the articles in each database and searched for relevant articles according to the predefined criteria. The data extraction was carried out and cross checked by two independent reviewers according to the developed criteria. If necessary, the authors of the original articles were contacted to obtain detailed information on implementation of the trial, and disagreements were resolved by discussions between the two reviewers or a third reviewer (Zhan et al., 2013).

Statistical analysis

Cochrane systematic review software RevMan 5.2 (http://handbook.cochrane.org) (Cochrane systematic review software RevMan 5.2, 2013) was used for the meta-analysis. A clinical and methodological heterogeneity analysis was performed for all included studies, and a subgroup analysis was then performed. The chi-square test was used for the statistical analysis; a probability value of 0.10 was considered to indicate statistical significance, and a P value of < 0.10 indicated heterogeneity between the results of the studies. The I^2 value was used for quantitative assessment (Higgins et al., 2003). Heterogeneity is not obvious when $I^2 < 25\%$, moderate heterogeneity exists when I^2 ranges from 25% to 50%, and greater heterogeneity exists when $I^2 > 50\%$. Heterogeneous test results are expressed with a random-effects model, and homogeneous test results are expressed with a fixed-effects model (Higgins et al., 2009). The effect size for efficacy was evaluated using interval estimation and hypothesis testing. The risk ratio (*RR*) was used for enumeration data, the weighted mean difference (*WMD*) was used for continuous variables, and interval estimation was performed using the 95% confidence interval (*CI*) (Higgins et al., 2003). The U test was used for hypothesis testing, and the results

are represented by Z and P values. The level of statistical significance was set at 0.05, and differences between curative effects were statistically significant at $P < 0.05$. The hypothesis test results are listed in a forest plot. When necessary, a sensitivity analysis was adopted to test the stability of the results (Higgins et al., 2003). Incomplete data were processed by intention analysis (Higgins et al., 2003). Descriptive analysis was adopted if heterogeneity was large between the two groups or the sources of heterogeneity could not be found (Higgins et al., 2003).

Results

Description of study

The literature search revealed 568 potentially relevant articles. After screening the titles and abstracts, 442 studies were excluded because they were repeated or were not clinical trials. The full text of the remaining 126 studies were retrieved for further assessment; of these, 114 articles were excluded because they did not meet the inclusion criteria or were RCTs, had invalid data, or were simple case reports. Finally, 12 RCTs were included in this review (**Figure 1**). All were published in China, and all results showed beneficial effects of XNKQ acupuncture.

Each study enrolled 20 to 100 patients (1,006 patients in total). All studies focused on the XNKQ needling method, which was accompanied by conventional medicine in some of the studies. In all studies, comparison was performed between the XNKQ needling method and either traditional acupuncture or conventional medicine. Two studies (Liu et al., 2006; Rao et al., 2006) described the mortality and disability rates, four studies (Liu et al., 2006, 2012; Rao et al., 2006; Liu and Chen, 2012) described the safety, four studies (Chen and Li, 2006; Liu et al., 2006; Rao et al., 2006; Xiong et al., 2006) described the activities of daily living (Barthel index), nine studies (Chen and Li, 2006; Xiong et al., 2006; Pi et al., 2007; Wang and Gao, 2008; Xiong et al., 2011; Yang et al., 2011; Guo, 2012; Liu and Chen, 2012; Liu et al., 2012; Wang et al., 2013) described the clinical efficacy, and no studies described the relevant economic indicators. Outcome data of all studies (Chen and Li, 2006; Liu et al., 2006, 2012; Rao et al., 2006; Xiong et al., 2006; Pi et al., 2007; Wang and Gao, 2008; Xiong et al., 2011; Yang et al., 2011; Guo, 2012; Liu and Chen, 2012; Liu et al., 2012) were integrated. All selective outcome reporting judgments were "yes." Other sources of bias were unclear. The details and features of the included studies are shown in **Additional Table 1**.

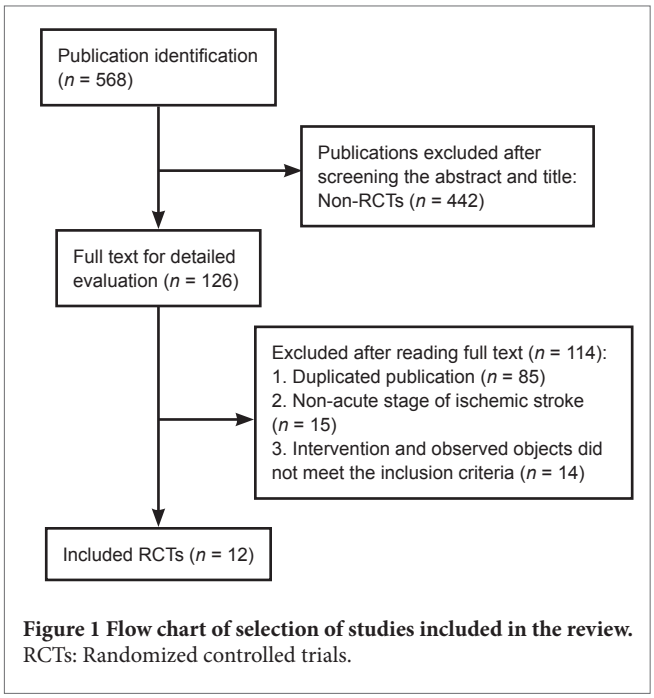

Figure 1 Flow chart of selection of studies included in the review.
RCTs: Randomized controlled trials.

Assessment of risk of bias

The average assessment of quality was based on the method described in the Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0. All studies had a generally high or uncertain risk of bias except in the domains of random sequence generation. Among the 12 RCTs, 7 (Chen and Li, 2006; Liu et al., 2006; Rao et al., 2006; Pi et al., 2007; Wang and Gao, 2008; Xiong et al., 2011; Guo, 2012) reported the detailed randomization methods. Among these seven

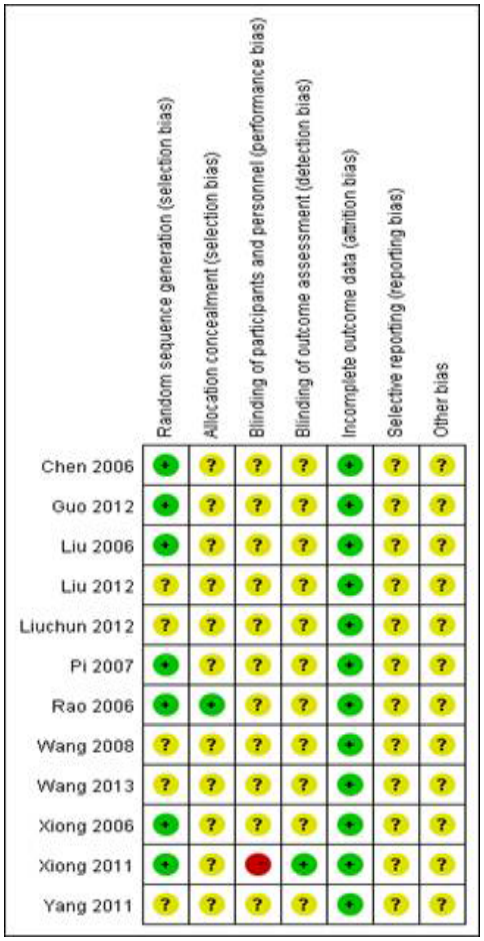

Figure 2 Risk of bias summary: review of authors' judgments about each risk of bias item for each included study.
+: "Yes," indicating a low risk of bias, -: "No," indicating a high risk of bias, ?: "Unclear," indicating insufficient information for this judgment.

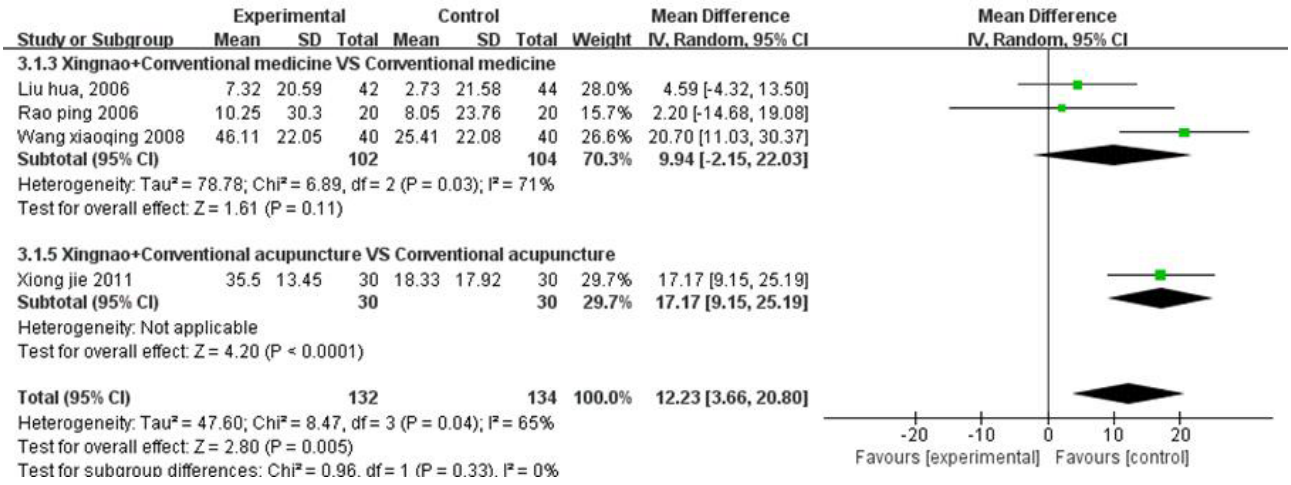

Figure 3 Forest plot presenting the study and subgroup meta-analysis for activities of daily living (Barthel index) of the *Xingnao Kaiqiao* needling method for acute ischemic stroke.
SD: Standard deviation; *CI*: confidence interval; I^2: statistical index of heterogeneity.

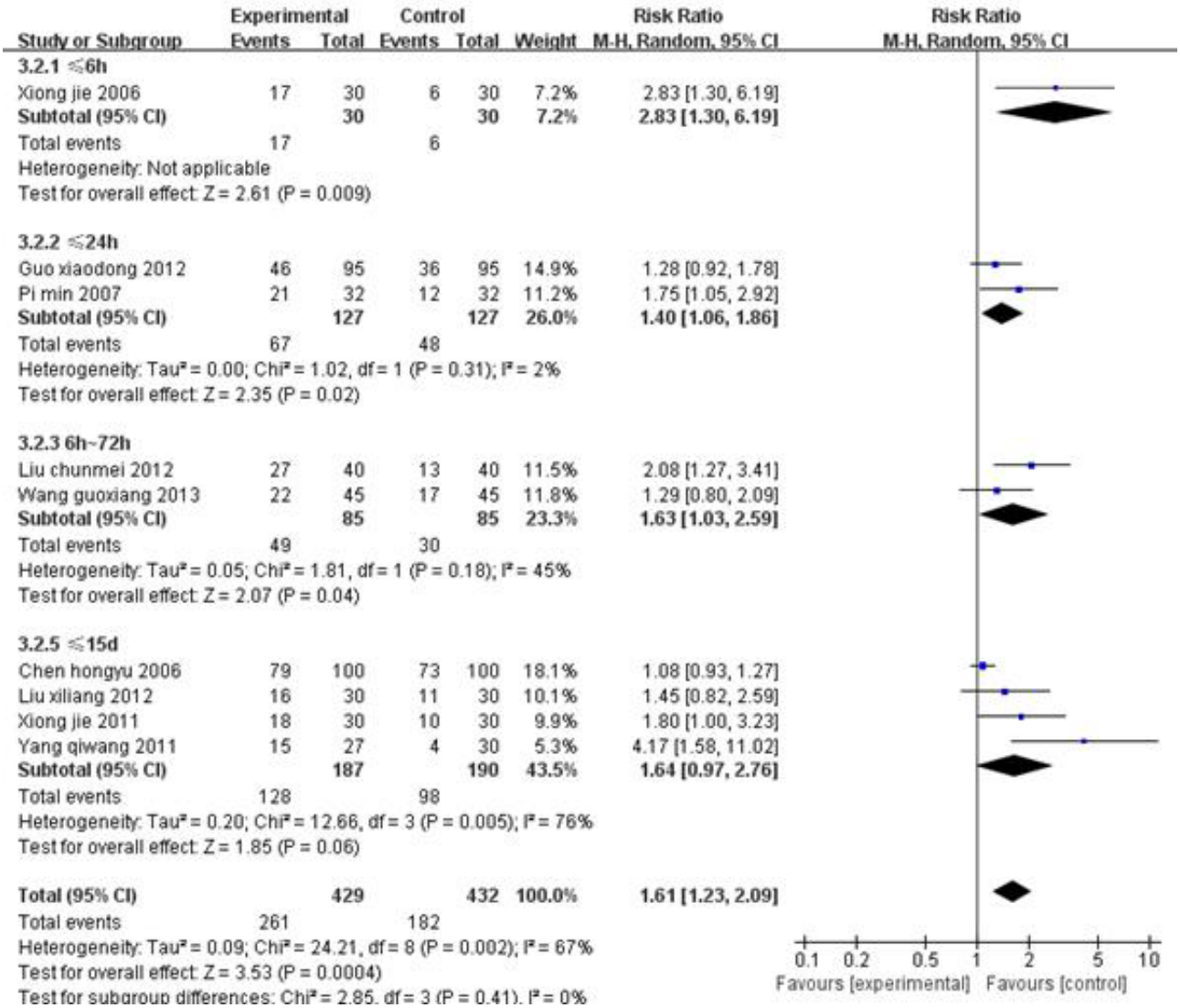

Figure 4 Forest plot presenting the study and subgroup meta-analysis for the clinical efficacy of the *Xingnao Kaiqiao* needling method for acute ischemic stroke.
M–H: Mantel–Haenszel method; *CI*: confidence interval; I^2: statistical index of heterogeneity.

trials, three (Liu et al., 2006; Rao et al., 2006; Xiong et al., 2011) adopted computerized randomization methods, and the other four trials (Chen and Li, 2006; Liu et al., 2006; Rao et al., 2006; Pi et al., 2007; Wang and Gao, 2008; Guo, 2012) adopted randomized digital tables. Only one study (Rao et al., 2006) reported whether allocation concealment was attempted. All studies except one (Guo, 2012) had a high risk of performance bias because of the unblinded nature of open comparison and did not report whether the outcome assessors were blinded. No RCTs mentioned whether drop-out or loss to follow-up occurred during the study; thus, uncertain risk of bias was given in the domain of incomplete outcome reporting. No studies provided information about any discrepancy between the original trial protocol and the reported results or trial registration number. As a result, uncertain risk of bias was also given in the domain of selective outcome reporting. The risk of bias of each RCT is illustrated in **Figure 2**. According to this measure, the studies were insufficient in terms of adequate randomization, concealed allocation, patient blinding, assessor blinding, and similar outcome assessment.

Results of meta-analysis

Among the three studies (Liu et al., 2006, 2012; Rao et al., 2006) that indicated the mortality and disability rates at the end of treatment or final follow-up (≥3 months), no clinical or statistical heterogeneity was present. A fixed-effects model was adopted for the meta-analysis (Yang et al., 2015), and significant differences were found in the disability rate but not in mortality. Nevertheless, for mortality, the horizontal line of the combined effect size RR intersected and was located to the left side of the equivalent vertical line. These results indicate that among patients with ischemic stroke, the XNKQ needling method more effectively reduced mortality and disability than did other treatments in the control group.

Adverse reactions

No adverse reactions were reported in the three studies (Liu et al., 2006, 2012; Rao et al., 2006).

Health-economic indicators

None of the included studies (Chen and Li, 2006; Liu et al., 2006, 2012; Rao et al., 2006; Xiong et al., 2006; Pi et al., 2007; Wang and Gao, 2008; Xiong et al., 2011; Yang et al., 2011; Guo, 2012; Wang et al., 2013) reported the cost or other health-economic indicators.

Activities of daily living (Barthel index) at end of treatment or final follow-up (≥3 months)

The activities of daily living (Barthel index) were reported in four studies (Liu et al., 2006; Rao et al., 2006; Xiong et al., 2006; Guo, 2012). Heterogeneity was tested for these data: $P = 0.04 < 0.1$, $I^2 = 65\%$, demonstrating that the included studies had clinical or statistical heterogeneity and could be analyzed using a random-effects model in the meta-analysis. For the combined effect size, *WMD* = 12.23, 95% *CI:* = 3.66–20.08, $z = 2.80$, and $P < 0.005$, indicating statistical significance. These results indicate that the XNKQ needling method was more effective than the control treatments. Subgroup analyses were performed because of clinical heterogeneity: three studies (Chen and Li, 2006; Liu et al., 2006; Rao et al., 2006) compared the XNKQ needling method combined with conventional medicine versus conventional medicine alone. In the heterogeneity test, $P = 0.03 < 0.1$ and $I^2 = 71\%$, demonstrating clinical or statistical heterogeneity; thus, a random-effects model was used in the meta-analysis. For the combined effect size, *WMD* = 9.94, 95% *CI*: −2.15–22.03, $z = 1.61$, and $P = 0.11 > 0.0001$, indicating no statistical significance; however, the horizontal line of the combined effect size WMD intersected the equivalent vertical line, showing that the XNKQ needling method tended to improve the daily lives of patients with ischemic stroke. One study (Guo, 2012) compared XNKQ acupuncture combined with conventional acupuncture versus conventional acupuncture alone. The results showed that the XNKQ needling method was more effective than the control treatments in terms of improving daily life of patients with acute ischemic stroke (**Figure 3**).

Clinical efficacy at end of treatment or final follow-up (≥3 months)

The clinical efficacy was reported in nine studies (Chen and Li, 2006; Pi et al., 2007; Wang and Gao, 2008; Xiong et al., 2011; Yang et al., 2011; Guo, 2012; Liu and Chen, 2012; Liu et al., 2012; Wang et al., 2013). In the heterogeneity test, $P = 0.002 < 0.1$ and $I^2 = 67\%$, demonstrating that the included studies had clinical or statistical heterogeneity and could be analyzed using a random-effects model in the meta-analysis. For the combined effect size, *RR* = 1.61, 95% *CI*: 1.23–2.09, $z = 3.53$, and $P = 0.0004$, indicating statistical significance. These results indicate that the XNKQ needling method was better than the control treatments. Subgroup analyses of different rehabilitation courses were performed because of the clinical heterogeneity. Four studies (Chen and Li, 2006; Xiong et al., 2011; Yang et al., 2011; Liu et al., 2012) reported that the course was 15 days. In the heterogeneity test, $P = 0.005 < 0.1$ and $I^2 = 76\%$, demonstrating that the included studies had clinical or statistical heterogeneity and could be analyzed using a random-effects model in the meta-analysis. For the combined effect size, *RR* = 1.64, 95% *CI*: 0.97–2.76, $z = 1.85$, and $P = 0.06 > 0.05$, indicating no statistical significance. However, the XNKQ needling method tended to be superior to the control therapy. One study (Wang and Gao, 2008) in which the rehabilitation course was 6 hours showed that the clinical efficacy of the XNKQ needling method was superior to the control therapy; two studies (Pi et al., 2007; Xiong et al., 2011) reported that the course was 24 hours. In the heterogeneity test, $P = 0.31 > 0.1$ and $I^2 = 2\%$, demonstrating that the included studies had clinical or statistical heterogeneity and could be analyzed using a random-effects model in the meta-analysis. For the combined effect size, *RR* = 1.40, 95% *CI*: 1.06–1.84, $z = 2.36$, and $P = 0.02$, indicat-

ing no statistical significance. Two studies (Liu and Chen, 2012; Wang et al., 2013) reported that the course was 6 to 72 hours. In the heterogeneity test, $P = 0.18 > 0.1$ and $I^2 = 45\%$, demonstrating that the included studies had no clinical or statistical heterogeneity and could be analyzed using a fixed-effects model in the meta-analysis. For the combined effect size, *RR* = 1.63, 95% *CI*: 1.16–2.30, $z = 2.81$, and $P = 0.005$, indicating statistical significance. These results indicate that the clinical effect of the XNKQ needling method in patients with acute ischemic stroke in all rehabilitation courses (6, 24, and 6–72 hours) was better than the clinical effect of the control treatment (**Figure 4**).

Discussion

Summary of the main results

The main purpose of this study was to critically evaluate the efficacy of XNKQ acupuncture treatment for acute ischemic stroke (within 2 weeks of onset) (Yang and Shi, 2007; Dong and Yang, 2013). This systematic review included 12 clinical RCTs that evaluated the XNKQ needling method without any additional conventional medicine in comparison with either traditional acupuncture or conventional medicine. We found that the XNKQ needling method might significantly reduce the disability rate, show improved clinical efficacy, and enhance patients' activities of daily living (Barthel index), but it had no significant impact on mortality. We also assessed the safety of XNKQ acupuncture in treating acute ischemic stroke. No severe adverse events were reported in any of the trials. Adverse reactions such as local hematoma formation and pain caused by individual differences in physique and improper acupuncture manipulation spontaneously resolved without any treatment (Chung et al., 2014).

Potential influencing factors

In the primary outcome analysis, XNKQ acupuncture had no significant benefit with respect to the mortality rate. However, this result should be interpreted with caution because it relies on data from only three trials (Liu et al., 2006, 2012; Rao et al., 2006) with small sample sizes and low methodological quality. Additionally, different degrees of neurologic impairment may have different effects on the mortality of stroke. Because most of the included studies did not provide a detailed description of the characteristics of the patients' neurological dysfunction, we were unable to explore this issue further. Finally, the follow-up periods (≤ 6 months) were relatively shorter than in trials testing various surgical or nonsurgical interventions for acute ischemic stroke, which assessed 2-year outcomes after the treatment intervention (Wei et al., 2011). Thus, the longer-term effects of the XNKQ needling method could not be assessed in our analyses.

Study limitations

Although this review provides many useful findings, it has several limitations. First, no economic evaluation data were provided in the included studies; therefore, no economic reference is available for clinicians and health policy makers. At present, the treatment expense due to stroke is one of the greatest burdens on the health care system in both developed and developing countries. In the future, health policy should focus on shortening hospital stays and reducing the disability rate (Kaur et al., 2014). Second, although strong efforts were made to find all relevant trials in many databases, our comprehensive search may not have removed all publication- or language-related bias. Third, the included trials were applied in various ways; they differ in terms of the study design, sample size, outcome measurement, and characteristics of patients (Magin et al., 2013; Lee et al., 2014). Finally, these trials lacked standard outcome tools. Only a few trials employed objective measures, and no study used a sham group for comparison. Comparison of trials is difficult when the choice of outcomes is so heterogeneous. Future trials should be thoroughly focused on the experimental design. Large-scale RCTs with elaborate designs are needed to further verify the efficacy and safety of the XNKQ needling method in patients with acute ischemic stroke.

Directions for future research

The current study shows that the XNKQ needling method is safe and effective for acute ischemic stroke. However, the total number of included RCTs and methodological quality was too low to draw a firm conclusion, and the strength of the current analysis may have been affected by the limitations. More evidence-based studies should be carried out to provide more reliable data.

Author contributions: *ZXY participated in the study concept, design and wrote the paper. JHX and DDL were responsible for data integration and analysis. All authors approved the final version of the manuscript.*
Conflicts of interest: *None declared.*
Data sharing statement: *The datasets analyzed during the current study are available from the corresponding author on reasonable request.*
Plagiarism check: *Checked twice by iThenticate.*
Peer review: *Externally peer reviewed.*

Additional file: *Additional Table 1 Characteristics of trials included in this review.*

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