

## SYSTEMATIC REVIEW

## Qingkailing injection for the treatment of acute stroke: a systematic review and Meta-analysis

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### Abstract

**OBJECTIVE:** To evaluate systematically the clinical efficacy and safety of Qingkailing (QKL) injection in the treatment of acute stroke.

**METHODS:** Searches for randomized controlled trials into acute stroke treated with QKL injection were performed in the China National Knowledge Infrastructure Database, China Science and Technology Journal Database, Wan fang Database, Chinese Biomedical Literature Database, PubMed and Cochrane Library, from January 1979 to March 2013. Two reviewers independently retrieved the RCTs and extracted the information. The Cochrane risk of bias method was used to assess the quality of the included studies, and a Meta-analysis was conducted with Review Manager 5.2 software.

**RESULTS:** A total of 13 studies with 1110 participants were included. The quality of the

studies was generally low. The Meta-analysis indicated that the combined use of QKL and Western Medicine was significantly superior to control group therapy in terms of the total effective rate. The relative risk (RR) in the acute cerebral hemorrhage (ACH) sub-group was 1.17 [95% confidence interval (CI) (1.08, 1.26),  $P=0.0001$ ]. In the acute cerebral infarction (ACI) sub-group, RR was 1.27 [95% CI (1.14, 1.42),  $P<0.0001$ ], and in the ACH and ACI mixed sub-group, RR was 1.34 [95% CI (1.20, 1.50),  $P<0.0001$ ]. Additionally, QKL promoted the absorption of hematoma [mean difference (MD)= - 3.73, 95% CI ( - 4.48, - 2.98),  $P<0.0001$ ], decreased neurological damage in ACI [MD= - 5.60, 95% CI ( - 8.50, - 2.70),  $P=0.0002$ ] and ACH [MD= - 4.08, 95% CI ( - 8.00, - 0.16),  $P=0.04$ ], promoted the recovery of awareness [RR=1.56, 95% CI (1.09, 2.21),  $P=0.01$ ] and reduced the whole blood viscosity coefficient [MD= - 0.75, 95% CI ( - 1.47, - 0.03),  $P=0.04$ ]. There were no adverse drug reactions reported in the included studies.

**CONCLUSION:** Based on this systematic review, QKL combined with conventional therapy was effective compared with control treatment. However, because the articles used in the study were not of high quality, further studies should be conducted into the efficacy and safety of QKL in treating acute stroke.

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**Key words:** Qingkailing injection; Stroke; Acute cerebrovascular disease; Meta-analysis; Randomized controlled trials; Review

## INTRODUCTION

In Western Medicine (WM), acute stroke is also known as acute cerebrovascular disease. It includes acute cerebral infarction (ACI), acute cerebral hemorrhage (ACH), cerebral embolism and subarachnoid hemorrhage.<sup>1</sup> Stroke can be divided into two types: ischemic stroke and hemorrhagic stroke. Ischemic stroke includes cerebral infarction and cerebral thrombosis, and the most common case of hemorrhagic stroke is cerebral apoplexy. Stroke has one of the highest incidences of the cerebrovascular diseases. It results in high rates of morbidity, mortality and disability, and often contributes to sequelae that may seriously threaten human health. The majority of survivors (60%) require the help of medical institutions; their lives may be dramatically affected and the possibility of recurrence is high. At the same time, stroke is one of the most expensive diseases to treat, which can bring a great deal of economic burden to patients.<sup>2-4</sup> Results of some studies have shown that the incidence of stroke is increasing. Therefore, methods to treat acute stroke effectively and reduce the impact of its sequelae have become foci for research.<sup>5</sup>

Qingkailing injection (QKL) is derived from Angongniuhuang pills. Its main ingredients include Niu Huang (*Calculus Bovis*), Shuiniujiao (*Cornu Bubali*), Huangqin (*Radix Scutellariae Baicalensis*), Jinyinhua (*Flos Lonicerae*), and Zhizi (*Fructus Gardeniae*). It has a variety of functions: as an antifebrile agent and hepato-protectant, in regulating immunity, promoting the absorption of intracranial hematoma and reducing cerebral edema.<sup>6</sup> QKL is used widely in the clinical setting in the areas of cerebrovascular disease, acute infectious diseases, pediatric diseases and otorhinolaryngologic diseases, among others. It has achieved significant effects in the treatment of stroke, hepatitis, and in cardiovascular and pediatric diseases.<sup>7</sup> Recently, more and more clinical cases have been reported describing QKL as an emergency treatment for acute stroke with fever.<sup>8</sup> All of these reports have shown that QKL could increase the efficacy rate of emergency rescue in Traditional Chinese Medicine (TCM).

Although there have been several previous Meta-analyses regarding stroke,<sup>9-13</sup> their focus has been on either cerebral infarction or cerebral hemorrhage only. Rather, this systematic review aims to evaluate objectively the efficacy and safety of QKL in treating acute stroke without classification, providing a scientific basis for its clinical use in acute stroke, the reason of no classification was QKL was efficacy in both hemorrhagic and ischemic stroke that indicated in one study.<sup>14</sup>

## MATERIALS AND METHODS

### Study search

Two reviewers retrieved randomized controlled trials

(RCTs) by searching the following databases from January 1979 to March 2013: the China National Knowledge Infrastructure Database, Wan fang Database, China Science and Technology Journal Database, Chinese Biomedical Literature database, PubMed, and the Cochrane Library. The search terms included "Qingkailing" as a MeSH term and then "stroke or cerebrovascular diseases" for secondary retrieval. Studies published in English or Chinese were considered.

### Inclusion criteria

Studies meeting the following criteria were included. Clinical RCTs used QKL to treat acute stroke, regardless of blinding. The diagnostic criterion in terms of TCM was "apoplexy diagnostic efficacy assessment standards"; that used in terms of WM was "the various types of cerebrovascular disease diagnostic points", as determined in 1995.<sup>15</sup> Diagnoses were validated using computer tomography or magnetic resonance imaging scanning. The courses of disease were 7 days or shorter; this is considered the acute phase of stroke. All patients were experiencing the first onset of stroke, and no limits were placed on age, gender, race or severity of disease. The control group was treated with predominantly two types of conventional WM: patients with cerebral hemorrhage received hemostatics, drugs lowering intracranial pressure, anti-hypertensives and anti-infectives; patients with cerebral infarction received vasodilators and anti-hyperlipidemics. Both types of patients required brain cell activators. The experimental group was treated with WM on the same basis as the control group, but combined with QKL. None of the therapies was combined with any other Chinese medicine, surgery or acupuncture. The dosages and treatment courses were not limited. The primary outcome was the total effective rate, using the following formula: total effective rate=(number of recovered patients + number of patients with significant progress + number of patients with progress)/total number × 100% . Efficacy criteria predominantly referred to a reduction in the neurological deficit score, and to the living ability of patients (or the degree of disability). Recovery was determined when the functional deficit score decreased by between 90% and 100%, and the degree of disability was 0. Significant progress was determined when the functional deficit score decreased by between 46% and 89%, and the degree of disability was 1. Progress was determined when the functional deficit score decreased by between 18% and 45%. No change or deterioration was determined when the functional deficit score decreased by <18%.<sup>15</sup> Secondary outcomes were: the degree of absorption of cerebral hematoma, the improvement of neurological deficits, restoration of awareness (based on the duration of patients' unconsciousness, and wake-up time), hemorheology index, and the number of adverse drug

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