CRD summary
This review assessed the effectiveness of Danshen (a Chinese herb) in improving disability after acute ischaemic stroke. The authors concluded that there was no evidence that Danshen improves disability after acute ischaemic stroke. This was a well-conducted review that identified generally poor-quality studies. The evidence presented supports the authors’ conclusion.

Authors’ objectives
To assess the effectiveness of Danshen (a Chinese herb) in improving disability after acute ischaemic stroke, and examine the quality of the evidence.

Searching
MEDLINE (1966 to June 2003), EMBASE (1980 to December 2002), the Cochrane Controlled Trials Register (Issue 4, 2002) and CBM-disc (1979 to 2002) were searched; the keywords were reported. In addition, the Shanghai Chinese-Medicine and Pharmacology Journal (1990 to 2002), references from retrieved studies and reviews, and traditional Chinese medicine conference proceedings were handsearched.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies that compared any preparation of Danshen with any placebo, or western or herbal preparation, not containing Danshen were eligible for inclusion.

The included studies compared Danshen ('Compound Danshen Injections' 12 to 30 mL intravenously per day) with western medicine (Buflomedil, Carnitine, Acuthrombin-B, Naloxone, PGE1, Antithrombin and FDP) or Chinese herbal medicines (Radix puerariae and Honghuayou). In most studies treatment with Danshen lasted 14 to 15 days (range: 10 to 28); control treatments lasted from 3 to 28 days. None of the included studies compared Danshen with placebo.

Participants included in the review
Studies of patients within 7 days of an acute ischaemic stroke (cerebral infarction or cerebral embolism) who had been diagnosed clinically and by computed tomography or magnetic resonance imaging were eligible for inclusion. In the included studies, the mean age of the patients was 61 years, 60% had moderate to severe stroke, and the mean interval from stroke onset was 4 days.

Outcomes assessed in the review
Studies that assessed disability using measures that were either internationally recognised or nationally approved by an academic body in China were eligible for inclusion.

The primary review outcome was change in disability at 2 weeks, as measured on the Chinese National Disability Scale which classifies disability into five categories. In the review, the categories were combined to give a dichotomous measure of disability: ‘improved’ for the categories cure, significant improvement and improvement, and ‘not improved’ for the categories no improvement and deterioration. The included studies assessed disability after 10 to 28 days.

How were decisions on the relevance of primary studies made?
Two reviewers searched the electronic databases and one reviewer conducted the handsearches. Two reviewers independently selected studies published in English and Chinese and resolved any disagreements through discussion.

Assessment of study quality
Validity was assessed and scored using the Jadad scale, which considers the reporting and handling of randomisation, blinding and handling of withdrawals. Studies were also assessed for individual quality criteria, intention-to-treat analysis, drop-outs and sample size. It appeared that at least two reviewers assessed validity.

Data extraction
Two reviewers independently extracted the data and resolved any disagreements through discussion. The number and percentage of patients in each category of disability change were extracted for each treatment group for each study, and the odds ratio (OR) of improvement at 2 weeks was calculated, along with 95% confidence interval (CIs), for Danshen compared with other preparations.

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative. Where more than one study compared Danshen with the same control, the pooled OR and 95% CIs were calculated using a random-effects model (DerSimonian and Laird) in the presence of statistically significant heterogeneity, and a fixed-effect model (Mantel Haenszel model) in its absence.

How were differences between studies investigated?
Statistical heterogeneity was tested using the chi-squared test. Where significant heterogeneity was found, characteristics of the studies and patients that might be responsible for this heterogeneity were examined.

Results of the review
Eleven RCTs (n=975) were included.

The studies were generally of a poor quality: 3 RCTs scored 2 out of 5 points and the other 8 RCTs scored 1 point.

Methodological limitations included small sample size (8 RCTs had 50 to 100 patients), no reporting of methods used for randomisation (8 RCTs), no clear reporting of inclusion and exclusion criteria (9 RCTs), and no reporting of drop-outs or death (6 RCTs). None of the RCTs reported blinding or the use of intention-to-treat analysis.

Five RCTs showed that Danshen was inferior to Buflomedil, Acuthrombin-B, Naloxone, Antithrombin and Radix puerariae. The other 6 RCTs found no significant difference between Danshen and Buflomedil, PGE1, Carnitine, Naloxone, FDP and Honghuayou.

The meta-analysis showed Danshen was significantly inferior to Buflomedil (2 RCTs; OR 0.27, 95% CI: 0.12, 0.61). Significant statistical heterogeneity was found (P=0.083). The RCTs assessed outcomes after different time periods (14 and 28 days).

The meta-analysis also showed Danshen was significantly inferior to Naloxone (2 RCTs; OR 0.16, 95% CI: 0.07, 0.40). No significant statistical heterogeneity was found (P=0.29).

Authors’ conclusions
There was no evidence that Danshen improved disability after acute ischaemic stroke.

CRD commentary
The review addressed a clear question in terms of the participants, intervention, outcomes and study design. Several relevant sources were searched and attempts were made to reduce publication and language bias. Two reviewers
independently selected studies and extracted the data, thus reducing the potential for bias and errors. Validity was assessed using specified established criteria and the results of the assessment was discussed.

There was adequate information on the included studies. The studies were combined in a narrative, with meta-analysis only conducted where studies compared the same treatments. Statistical heterogeneity was assessed and meta-analysis graphs were presented. Although significant heterogeneity was found for the meta-analysis of Buflomedil, both studies showed similar direction of treatment effect. Where significant heterogeneity was found potential reasons were suggested. This was generally a well-conducted review and the evidence presented supports the authors’ conclusion.

Implications of the review for practice and research
The authors did not state any implications for practice or further research.

Bibliographic details

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.