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Efficacy and safety of Bi qi capsules in the treatment of cervical spondylosis: an update of the meta-analysis

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Abstract: *Background: At present, the treatment of cervical spondylosis by traditional Chinese medicine has attracted extensive attention. Studies have found that the efficacy of Bi qi capsules in the treatment of cervical spondylosis is different. Therefore, this study systematically evaluated the efficacy of Bi qi capsules or combined with conventional drugs for the treatment of cervical spondylosis. Meta-analysis of visual pain simulation (VAS) score and adverse reactions. Methods*: *From 8 databases of CNKI, VIP, Wan fang Data, CBM, PubMed, Web of science, Embase, and Cochrane Library, the data of Bi qi Capsules or combined conventional drugs for cervical spondylosis in the past 10 years from 2012 to July 2022 were retrieved. Randomized controlled trials were conducted to evaluate the efficacy, VAS score and adverse reactions of Bi qi Capsules on cervical spondylosis through a random-effects model system for meta-analysis. Results: Eight studies with 758 participants, 379 in the treatment group and 379 in the control group, were included in this study. Compared with the control group, the effective rate of Bi qi Capsule or combined with conventional drugs for cervical spondylosis was significantly improved, the VAS score was significantly lower than that of the control group, and the occurrence of adverse reactions was not significantly different from that of the control group. Conclusion: Bi qi Capsule is safe and effective in the treatment of cervical spondylosis and can significantly reduce neck and shoulder pain.*

Keywords: *Bi qi capsule; cervical spondylosis; meta-analysis; effective rate; adverse reactions*

1. Introduction

As a common chronic intervertebral disc degenerative disease, cervical spondylosis has a high incidence rate and a younger age of onset. Active prevention and control are urgent [1]. Clinical studies have found that the prevalence of neck pain ranges from 0.4% to 86.8% [2], and the prevalence of cervical spondylosis in my country is also as high as 3.8% to 17.6% [3-4]. The main methods of treating cervical spondylosis are surgery and non-surgical treatment. Non-surgical treatment includes non-steroidal anti-inflammatory drugs, oral and external application of traditional Chinese medicine, acupuncture, physiotherapy massage, and moxibustion. Surgical treatment has the disadvantages of high surgical risk, insignificant postoperative improvement and easy recurrence. Clinical studies have found that Bi qi Capsules have high efficacy in the treatment of cervical spondylosis [5-12], but the reports are inconsistent. The author studies the effects of Bi qi Capsules on cervical spondylosis through a meta-analysis.

2. Methods

We conducted this study according to the guidelines in the Cochrane Manual for the Review of Systematic Interventions, version 5.3.0, and report its results according to systematic reviews and meta-analyses.

2.1 Search strategy

Eight databases including CNKI, VIP, Wan fang Data, CBM, PubMed, Web of science, Embase, and

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Cochrane Library were systematically searched. Search the domestic and foreign literature (Chinese and English literature) in the past 10 years from January 2012 to June 2022, and use the following Chinese keywords in (CNKI, VIP, Wan fang Data, CBM): (Bi qi Capsule) and (Cervical spondylosis, radicular cervical spondylosis, vertebral artery cervical spondylosis, sympathetic cervical spondylosis, etc.). English keywords used in English databases (PubMed, Web of science, Embase, Cochrane Library) are (Bi qi capsule, Bi qi) and (cervical spondylosis, nerve-root type cervical spondylosis).

2.2 Included studies

Studies were selected for inclusion by 2 independent reviewers (Liang Zhuang and Yang Lei) and approved by the corresponding author (Bo Dong). The process of study selection is shown in Table 1. Studies that meet PICOS (Participants, Interventions, Comparators, Outcomes, and Study Design) criteria. Inclusion criteria: (1) This study is a randomized controlled clinical trial; (2) The participants must have primary cervical spondylosis; (3) The treatment group in this study is Biqi Capsule or combined with conventional drugs for cervical spondylosis; 4) This study included any one of the following efficacies, VAS score or adverse reactions as outcome indicators.

2.3 Exclusion studies

Exclusion criteria: (1) Non-Chinese and English randomised controlled trials. (2) Animal experimental research. (3) Letters, conference abstracts, case reports, reviews, and review papers. (4) Studies with no control group intervention. (5) Secondary cervical spondylosis (such as tuberculosis, suppurative cervical spondylosis, or tumor, etc.). (6) The mean or variance results before and after the experiment are not fully recorded.

2.4 Data extraction and quality assessment

Extracting data detailed information was extracted from each included study by two investigators (Liang Zhuang and Yang Lei) independently using standardized templates. Such as the first author, publication year, sample size, age, course of disease, study design, interventions in the experimental group and control group, treatment dose and frequency of Biqi Capsule and control group, course of treatment, and outcome indicators. (Table 1)

Two authors independently assessed study quality and risk of bias for each eligible study using criteria outlined in the Cochrane Handbook (Higgins and Altman 2008). We considered 6 criteria (see Figure 1): (1) random sequence distribution generation; (2) allocation concealment; (3) blinding; (4) outcome data; (5) selective reporting; (6) other biases. These research projects are classified as high risk, low risk, and no clearance. In case of disagreement, follow the opinions of an independent researcher (Dong Bo). The data of dichotomous variables were expressed by odds ratio (OR), and the data of continuous variables were expressed by weighted mean difference (WMD), and each effect size was expressed by 95% confidence interval (CI). And the I2 test was used to analyze the heterogeneity of the included studies. When the heterogeneity among the studies was small (I2 ≤50% and P>0.1), the fixed effect model was used; when the heterogeneity was large (I2>50%) and P≤0.1), a random-effects model was used to conduct subgroup analysis to find the source of heterogeneity. If the number of articles was ≥ 10, a funnel plot was used to analyze potential publication bias for qualitative assessment. It was quantitatively assessed using Egger and Bgger's test. Publication bias was assessed using sensitivity analysis.

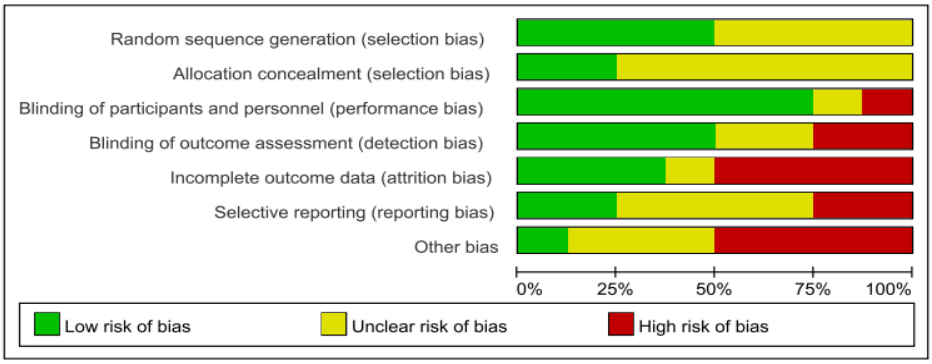

Figure 1: Risk Assessment Form

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3. Results

The flow chart of literature search is shown in Figure 2. Among the 378 articles obtained from 8 databases, CNKI, VIP, Wan fang Data, CBM, PubMed, Web of science, Embase, and Cochrane Library. 125 duplicate articles were removed, 205 articles were removed by reading titles and abstracts, including 81 non-randomized controlled trials, 36 review articles, 60 animal studies, and 28 articles with incomplete outcome information. After reading the full text and including 48 articles, 40 records were deleted. In the end, 8 eligible papers were included in the meta-analysis.

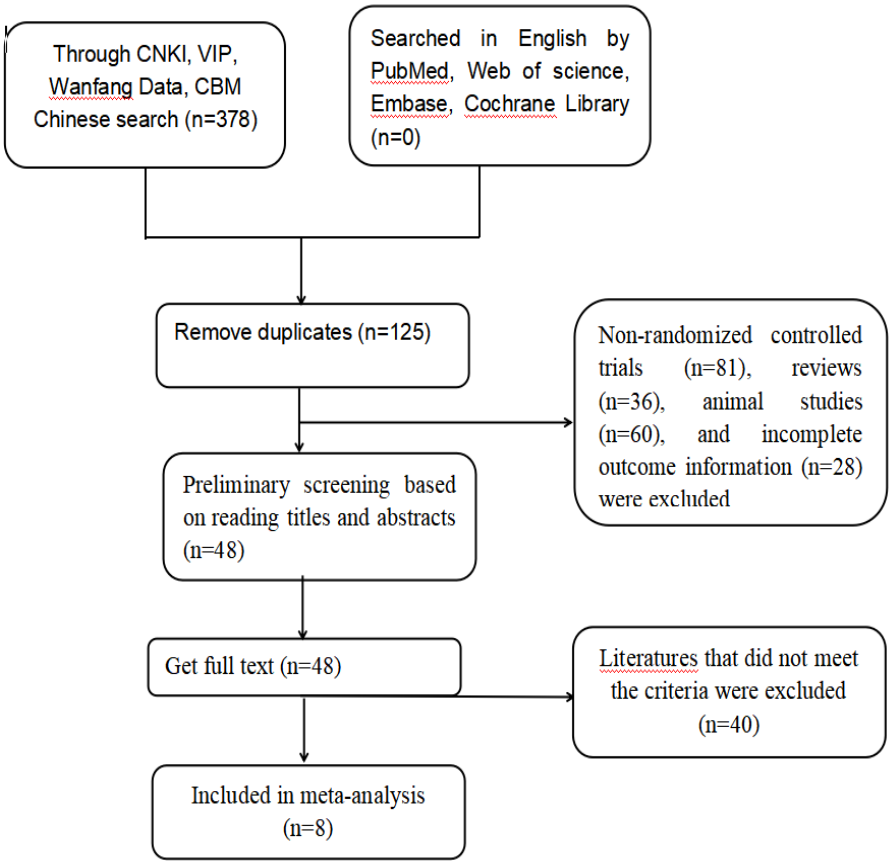

Figure 2: The flow chart of literature screening

3.1 Research characteristics and literature quality evaluation

The basic characteristics of the included studies are shown in Table 1. A total of 8 studies were included, and the study years were from 2012-2022. The sample size varied from 56 to 120 people. A total of 758 people were divided into treatment or control groups. (Risk of Bias in Research) According to the Cochrane Handbook, the results of our assessment of risk of bias are shown in Figure 2. A total of 8 literatures were included in this study, of which 1 used the random number method, 1 mentioned the random number table method, and 6 only mentioned random grouping. The method was not described in detail, and the accuracy of randomization could not be judged. None of the studies mentioned blinding and the risks were high. None of the 6 papers stated whether blinding and allocation concealment were used, and 1 mentioned follow-up, with no attrition bias and no other bias. Therefore, the risk of bias assessment tool was used to evaluate the quality of the included studies.

3.2 Analysis of the efficacy and safety of the treatment group and the control group

3.2.1 Effectiveness

There are 7 literatures (Figure 3) for efficient meta-analysis, and it is found that Biqi Capsules or combined with conventional KOA drugs have significantly higher clinical efficacy than conventional KOA drugs (RR) 1.13 (95% CI: 1.00, 1.28; I2 =0.0%, p=0.998). There is little heterogeneity. Egger

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(P=0.139>0.05), begg (P=0.099>0.05), there is no publication bias, and the results are relatively robust.

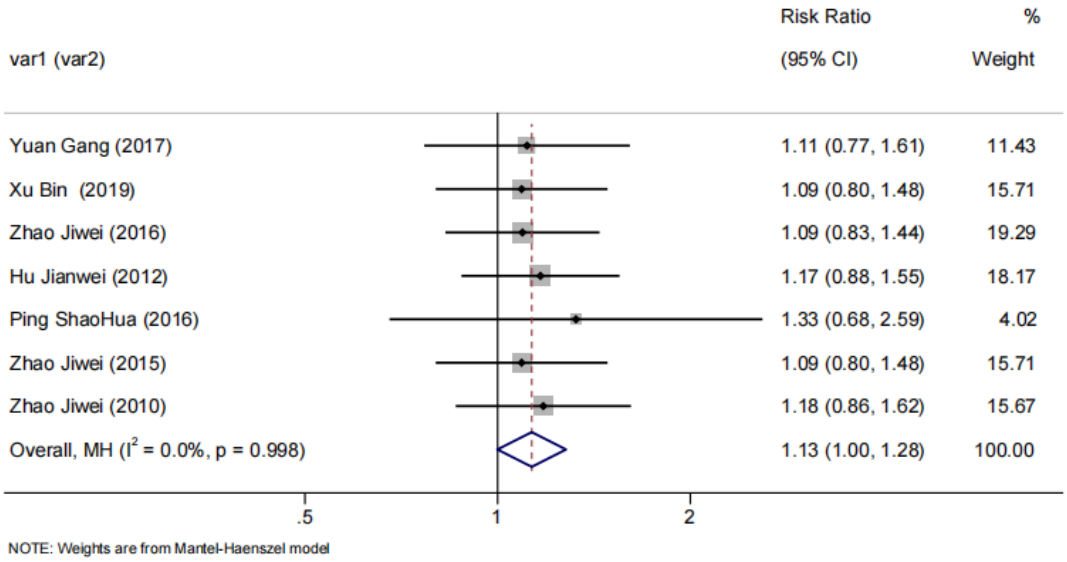

Figure 3: Efficiency

3.2.2 VAS score

Four literatures were included (Fig. 4) to study the change of VAS score, and it was found that the VAS score of Biqi capsule or combined with conventional treatment of cervical spondylosis drugs was significantly lower than that of conventional treatment of cervical spondylosis drugs (SMD) was -1.22 (95% CI: -1.60, -0.83; I2=99.5%, p=0.000). High heterogeneity.

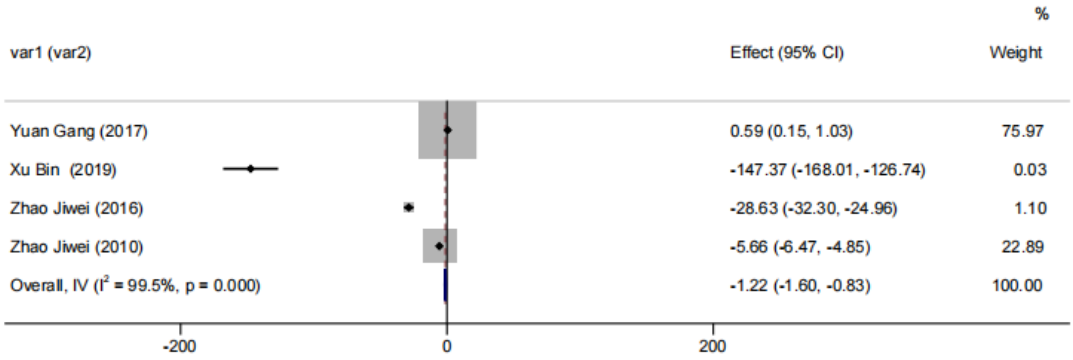

Figure 4: VAS score

3.2.3 Adverse reactions

There are 3 literatures (Figure 5) for meta-analysis, and it is found that there is no significant difference in the incidence of adverse reactions between Bi qi Capsules or combined with conventional drugs for cervical spondylosis compared with conventional drugs for cervical spondylosis (RR) 0.24 (95% CI: 0.05, 1.07; I2=0.0%, p=0.612). The heterogeneity is small, there is no publication bias, and the results are more robust.

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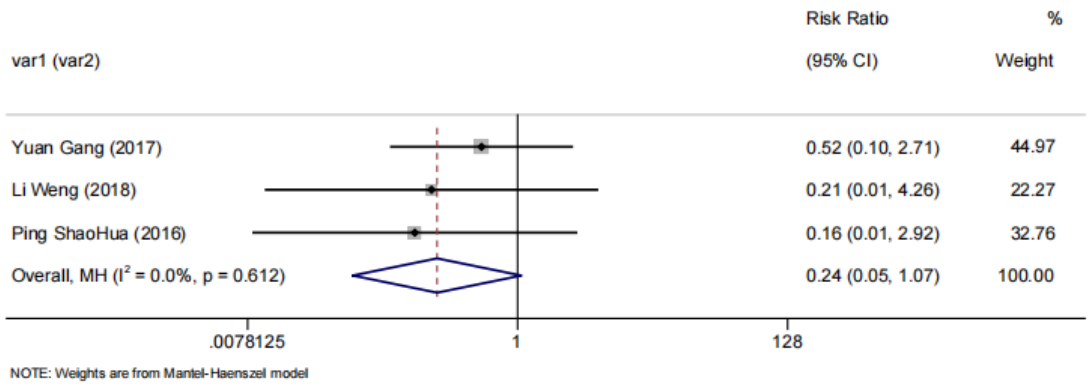

Figure 5: Adverse reactions

4. Discussion

The formula of Bi qi Capsules is derived from Huatuo's proven prescription of the Han Dynasty, "One Immortal Pill". The efficacy of rheumatism, pain relieving and blood circulation [13-14]. Modern research has found that the king drug strychnine has a strong analgesic effect and a faster speed, and salvia can improve the dilation of blood vessels, improve the microcirculation of the whole body, and accelerate the dissipation of inflammation. Codonopsis can promote microcirculation and improve the immunity of the body [15]. Panax notoginseng can prevent and treat arthritis and has a promoting effect on nerve regeneration [16]. Achyranthes can be anti-inflammatory and analgesic and improve the nervous immunity of the body [17]. Dilong has anticonvulsant effect; licorice can reduce strychnine toxicity and improve safety. Bi qi Capsule in the treatment of cervical spondylosis has anti-inflammatory, analgesic, improving immunity and repairing effects on nerve damage.

Through meta-analysis of the effective rate, VAS score and adverse reactions of the 8 included literatures, it was found that the effective rate of Bi qi Capsule or combined with conventional drugs for cervical spondylosis was significantly higher than that of the control group, and the VAS score was significantly lower than that of the control group. The occurrence was not significantly different from the control group. Therefore, Bi qi Capsules has a better curative effect in the treatment of cervical spondylosis and has a significant effect in relieving pain.

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Table 1 Basic information table

literature	Year	Course of disease (treatment group/control group)	Treatment group/control group	age (therapy group)	age (control group)	Allocation method	Course of treatment	Treatment Group Interventions	control group interventions	Detection Indicator
Yuan Gang	2017	2.75±2.21/3.35±2.39	41/41	43.63±5.91	41.94±6.03	random numbers	14d	Bi qi Capsules 1.2g/time BID	Aceclofenac sodium capsules 0.1g/time BID	①②③
Li Min	2018	/	30/30	28.9	28.3	random	28d	Bi qi Capsules 1.2g/time TID+Inflatable neck brace to fix the neck every 30minTID+Infrared	profen codeine sustained-release tablets 0.2g/time QD + inflatable neck brace to fix the neck every 30min TID + infrared	③
Xu Bin	2019	5.63±1.54/5.74±1.28	50/50	54.18±7.51	53.46±8.3	random number table	30d	Physiotherapy 15 minutes/time BID	Physiotherapy 15 minutes/time BID	①②
Zhao Jiwei	2016	12.6±2.5/12.9±2.2	60/60	66.8±1.2	65.9±1.4	random	28d	Bi qi Capsules 1.2g/time TID + control group	Acupuncture 30min/time QD	①②③
Hu Jianwei	2012	/	60/60	/	/	random	28d	Bi qi Capsules 1.2g/time TID + control group	Acupuncture 30min/time QD	①③
Ping Shao hua	2016	/	28/28	45.3±15.7	46.1±17.2	random	14d	Bi qi Capsules 1.2g/time TID + control group	Routine physiotherapy such as pre-traction, drug hot compress, intermediate frequency pulse, high potential	①②③
Zhao Jiwei	2015	7.8/8.2	50/50	39.8	38.7	random	28d	Bi qi Capsule 1.2g/time TID+ Manipulation and Cervical Traction	Diclofenac sodium tablets 75mg/time QD + manipulation and cervical traction	①
Zhao Jiwei	2010	7.8/ 8.2	60/60	39.8	38.7	random	28d	Bi qi Capsules 1.2g/time TID + control group	Technique 20min/time QD	①

① Effective rate ② VAS score ③ Occurrence of adverse reactions