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Efficacy and safety of Bi qi capsules in the treatment of lumbar disc herniation: A meta-analysis

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Abstract: *Background:At present, traditional Chinese medicine has attracted widespread attention in the treatment of lumbar disc herniation (LDH). Clinical studies have found that the efficacy of Bi qi Capsules on LDH is inconsistent. Therefore, this study systematically evaluated Bi qi Capsules or combined with conventional treatment. Meta-analysis was performed on the efficacy of LDH drugs, visual pain simulation (VAS) score, Japanese Orthopaedic Association Scores JOA score, and adverse reactions. Methods: Eight databases of CNKI, VIP, Wan fang Data, CBM, PubMed, Web of science, Embase, and Cochrane Library were searched for randomized controlled trials of Jin bi qi capsules or combined conventional treatment of LDH from the database establishment to June 2022. The efficacy, VAS score, JOA score and adverse reactions of Bi qi Capsules on LDH were evaluated by random effects model system for meta-analysis. Results: Six studies with 642 participants, 306 in the treatment group and 336 in the control group, were included in this study. Compared with the control group, the effective rate and JOA score of Bi qi Capsule or combined with conventional treatment of LDH were 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 LDH and can significantly reduce pain and improve lumbar function.*

Keywords: *Bi qi capsule, lumbar disc herniation, meta-analysis, effective rate, adverse reactions*

1. Introduction

Lumbar disc herniation (LDH) is mainly caused by intervertebral disc degeneration (related to age, occupation, gender, trauma, and overloading factors) [1], annulus fibrosus rupture, nucleus pulposus herniation and irritation or compression of nerve roots, The cauda equina nerve causes low back pain or lower extremity cramps and other symptoms, which is a common and frequently-occurring disease in orthopaedics [2-4], and the incidence rate of patients over 50 years old reaches 20-35% [5-7]. The main treatment methods for LDH are conservative treatment and surgical treatment. According to clinical research, surgical treatment has the disadvantages of large trauma, low satisfaction and easy recurrence [8-13]. Conservative treatment has the advantages of obvious curative effect, no trauma, and durable curative effect. In recent years, traditional Chinese medicine has become more and more popular in the treatment of LDH patients, mainly because traditional Chinese medicine has the advantages of good curative effect and few adverse reactions in the treatment of chronic diseases such as LDH [14-19]. The author found that Bi qi Capsule has a good effect in the treatment of LDH [20-25] in clinical practice, so a meta-analysis was conducted to evaluate it.

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.

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2.1 Search strategy

Eight databases including CNKI, VIP, Wan fang Data, CBM, PubMed, Web of science, Embase, and Cochrane Library were systematically searched. From the establishment of the database to June 2022, the domestic and foreign literature (Chinese and English literature) were searched, and the following Chinese keywords were used in (CNKI, VIP, Wan fang Data, CBM): (Bi qi Capsule) and (lumbago, lumbar disc herniation) Symptoms, lumbar disc herniation, lumbar disc herniation, lumbar disc herniation). English keywords used in (PubMed, Web of science, Embase, Cochrane Library) English databases are (Bi qi capsule, Bi qi) and (lumbar disc herniation, lumbar disc herniation lumbar disc herniation, Prolapse of lumbar disc, Low back pain).

2.2 Included studies

Studies were selected for inclusion by 2 independent reviewers (Liang Zhuang and Yang Lei) and approved by the corresponding author (He li yun). 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 lumbar disc herniation; (3) The treatment group of this study is Bi qi capsule or combined with conventional treatment for lumbar disc herniation Drugs; 4) This study includes any of the following efficacy, VAS score, JOA 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 lumbar disc herniation (such as tuberculosis, purulent lumbar disc herniation, 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

Table 1: Basic information table

literature	Year	Course of disease (treatment group/control group)	Treatment group/contral group	age (therapy group)	age (control group)	Allocation methodtreatment	Course of (day)	Treatment Group Interventions	control group interventions	Detection Indicator
Dong wen	2021	3.26±1.14year/3.15±1.03year	47/47	45.28±2.52	45.69±2.34	random	5	Control group + Biqi capsule 1.2g/time BID	250ml 20% Mannitol + 10mg Dexamethasone	①②③④
Zhao wen hua	2019	12.43±4.73month/12.77±4.65month	30/30	43.17±10.85	43.30±12.37	random	14	Biqi Capsules 1.2g/time BID + Massage	Diclofenac sodium enteric-coated tablet 50mg/time + massage	①②③④
Chen li jun	2010	10.07±7.88month/10.36±8.05month	39/39	46.37±5.38	47.25±6.13	random	14	Biqi Capsule 1.2g/time TID + Spinal Fixed-point Rotation Reduction	B vitamins + spine fixed-point rotation reduction method	①④
Kong lin qin	2014	6month-12year/5month-13year	30/30	42.00±7.31	46.00±10.12	random number table	28	Biqi Capsules 1.2g/time BID	Sodium Chloride 500mL+ATP 4mL+Coenzyme A2mL QD	①②
Yan zhi	2006	1week-4year/9day-3year	120/120	41.7	37.3	single blind	28	Biqi Capsules 1.2g/time TID	ibuprofen 0.2gTID	①④
Guo wei	2010	/	40/70	39.95±10.28	37.55±9.85	Not mentioned	20	Biqi Capsule 1.2g/time TID + Feng's Spinal Rotation Reduction	Fengshi Gutong Capsules 4 capsules/time TID + Feng's Spinal Rotation Reduction	③

① Effective rate ② VAS score ③ WOMAC score ④ Occurrence of adverse reactions

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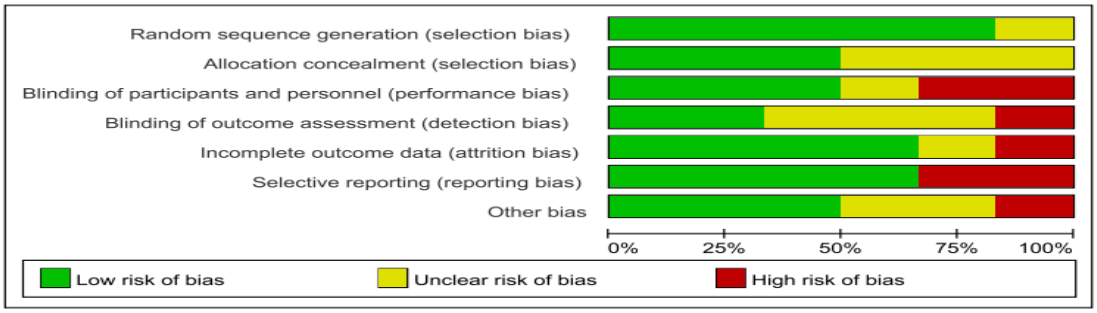

Figure 1: Risk Assessment Form

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 Bi qi 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.

3. Results

The flow chart of literature search is shown in Figure 2. A total of 146 articles were obtained from 8 databases of CNKI, VIP, Wan fang Data, CBM, PubMed, Web of science, Embase, and Cochrane Library. 78 duplicate articles were deleted, 49 articles were removed by reading title and abstract screening, including 18 non-randomized controlled trials, 12 review papers, 10 animal studies, and 9 articles with incomplete result information. After reading the full text and including 19 articles, 13 records were deleted. Finally, 6 eligible papers were included in the meta-analysis.

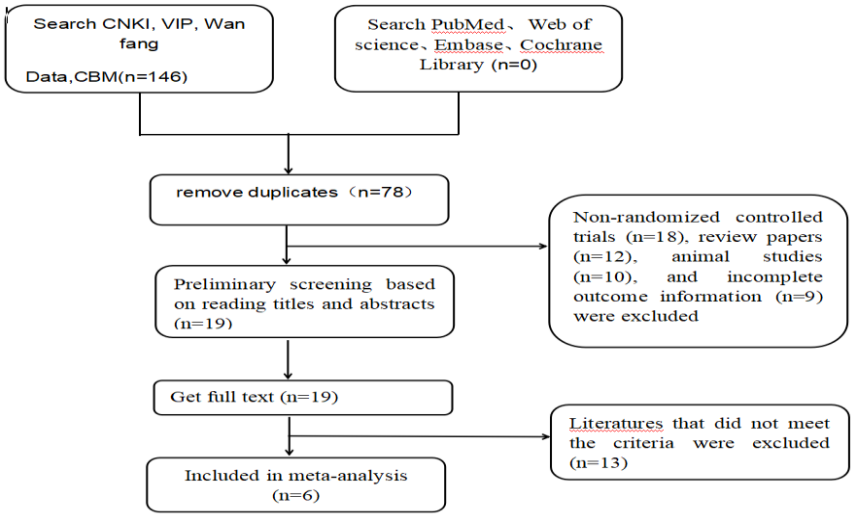

Figure 2: The flow chart of literature screening

ISSN 2706-6819 Vol.4, Issue 8: 53-59, DOI: 10.25236/IJFM.2022.040809

3.1 Research characteristics and literature quality evaluation

The basic characteristics of the included studies are shown in Table 1. in 6 studies. Five study outcome indicators were effective, 3 study outcome indicators had VAS score, and 3 study outcome indicators had JOA score. Adverse reactions were mentioned in 4 study outcomes. Sample sizes ranged from 60 to 240 people. A total of 642 people were divided into treatment and control groups. Participants' disease duration varied from 9 days to 13 years. Patients were aged <40 years in 1 study and ≥40 years in 5 studies. The results of our risk of bias assessment according to the Cochrane Handbook are shown in Figure 1. A total of 6 papers were included in this study, of which 1 used the random number method, 1 mentioned single-blindness, 3 only mentioned randomization, did not describe the method in detail, and could not judge the correctness of randomization, and 1 did not mention Methods of grouping, randomization and unmentioned grouping were at high risk of bias. None of the 5 literatures explained whether blinding and allocation concealment were used, and the risk was high. 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 were 5 literatures (Figure 3) for efficient meta-analysis, and it was found that Biqi Capsule or combined with conventional drugs for the treatment of lumbar disc herniation significantly increased the clinical efficacy (RR) 1.47 (95% CI) compared with conventional drugs for the treatment of lumbar intervertebral disc herniation: 1.25, 1.74; I2=78.4%, p=0.001). Heterogeneity was large (<10 included studies), so funnel plots were not used. Egger (P=0.935>0.05), begg (P=0.221>0.05), there is no publication bias, and the results are relatively robust.

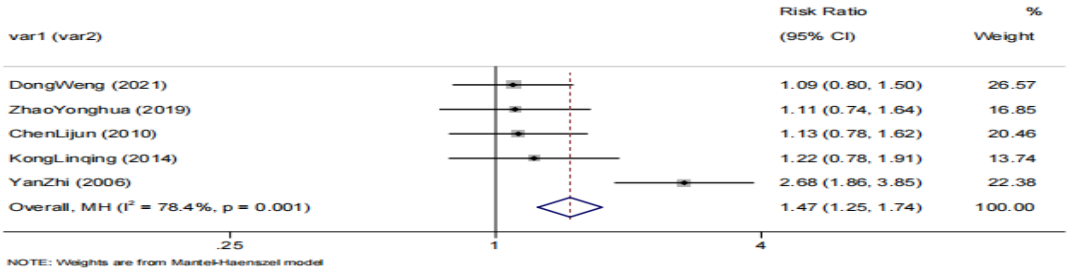

Figure 3: Efficiency

3.2.2 VAS score

Three literatures were included (Fig. 4) to study the change of VAS score, and it was found that the VAS score (SMD) of Biqi Capsule or combined with conventional treatment of lumbar disc herniation was significantly lower than that of conventional treatment of lumbar disc herniation (SMD), which was -5.54 (95% CI): -6.69, -4.40; I2=99.3%, p=0.000). High heterogeneity. Egger (P=0.963>0.05), begg (P=1>0.05), there is no publication bias, and the results are relatively robust.

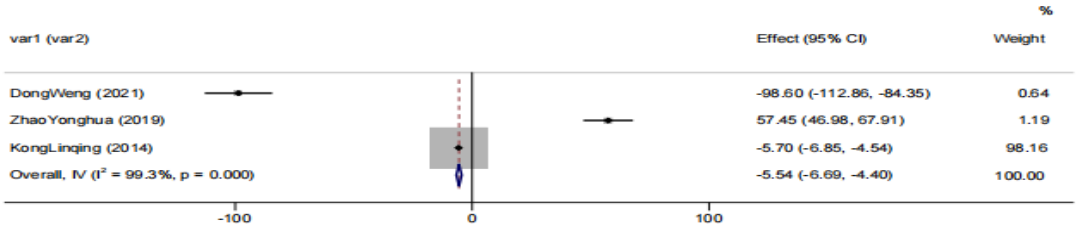

Figure 4: VAS score

3.2.3 JOA Score

Three literatures (Figure 5) studied the changes of JOA scores, and found that Biqi capsules or combined with conventional drugs for the treatment of lumbar disc herniation significantly improved the JOA score (SMD) of 1.20 (95% CI: 0.92) compared with conventional drugs for the treatment of lumbar disc herniation, 1.48; I2 = 95.7%, p = 0.000), high heterogeneity. Egger (P=0.281>0.05), begg

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(P=0.292>0.05), there is no publication bias, and the results are relatively robust.

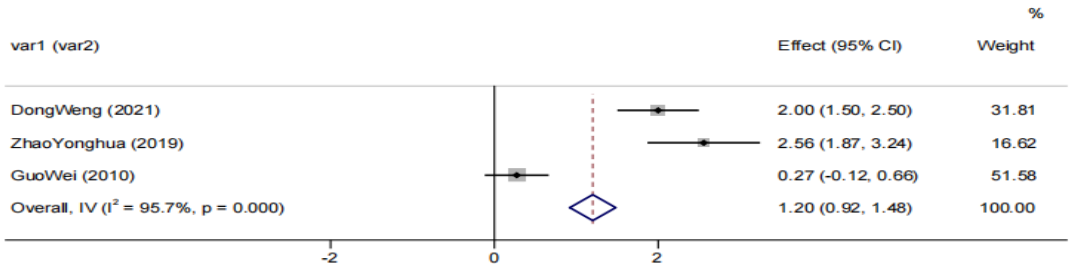

Figure 5: JOA Score

3.2.4 Adverse reactions

A meta-analysis of 4 literatures (Fig. 6) found that there was no significant difference in the occurrence of adverse reactions between Biqi capsules or combined with conventional drugs for the treatment of lumbar disc herniation compared with conventional drugs for the treatment of lumbar disc herniation. (RR) 0.48 (95% CI: 0.20, 1.15; I2=24.2%, p=0.267). There is little heterogeneity.

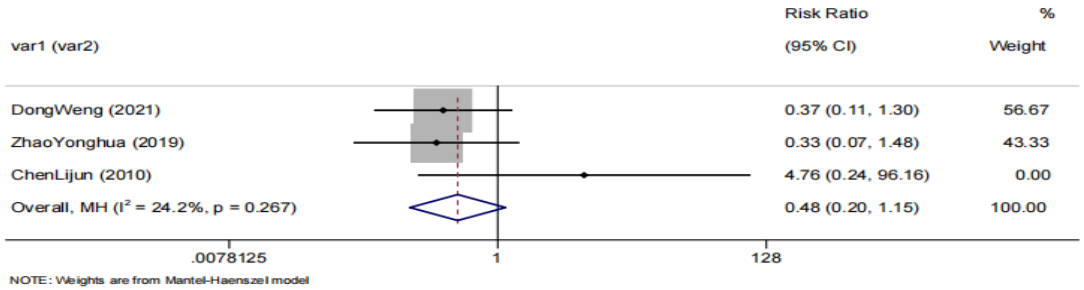

Figure 6: Adverse reactions

4. Discussion

Bi qi Capsule, as a classic clinical prescription for the treatment of Bi syndrome, was included in the 2015 edition of the Chinese Pharmacopoeia for the first time [26]. Dragon, Poria, Codonopsis, Licorice, Atractylodes, Panax notoginseng and other precious medicinal materials have the effects of nourishing qi and nourishing blood, dispelling rheumatism, relieving pain and promoting blood circulation [27-28]. Liu Yu xuan et al [29] found that the analgesic effect of Zhong bi qi Capsules in chronic neuropathic pain model rats was significantly higher than that of ibuprofen group. This conclusion is consistent with the clinical meta-analysis that Bi qi Capsule significantly reduces the VAS score compared with general LDH drugs.

The study found that Bi qi Capsules has good curative effect in the treatment of orthopedic diseases, including cervical spondylosis, knee osteoarthritis, ankylosing spondylitis, etc. We will conduct a meta-analysis for other diseases later. At present, the effective rate, VAS score, JOA score, and adverse reactions of Bi qi Capsule or combined with conventional drugs for the treatment of LDH have been updated and analyzed since the establishment of the database. However, it should be noted that there are some limitations of this study. First of all, all cases were included from China, and the sample size was small, no blinding and no hidden methods were mentioned.

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