JTCM 中医杂志 Journal of Traditional Chinese Medicine

Online Submissions:http://www.journaltcm.com
info@journaltcm.com

J Tradit Chin Med 2012 September 15; 32(3): 1-2
ISSN 0255-2922


EVIDENCE-BASED STUDY

# Heat-sensitive moxibustion for lumbar disc herniation: a meta-analysis of randomized controlled trials

Rixin Chen, Jun Xiong, Zhenhai Chi, Bo Zhang

**Rixin Chen, Jun Xiong, Zhenhai Chi, Bo Zhang**, Acupuncture and Rehabilitation Department, The Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine, Nanchang 330006, China; Key Laboratory of Heat-sensitive Moxibustion, State Administration of Traditional Chinese Medicine of People's Republic of China, Nanchang 330006, China; Acupoint Sensibility Laboratory, State Administration of Traditional Chinese Medicine of People's Republic of China, Nanchang 330006, China

**Supported by** the National "11th 5-year Plan" (2006BAI12B04-2); National Plan on Developing Key Basic Researches ("973" Plan) (2009CB522902); State Natural Science Fund (30760320); and a project of Key Sci-tech Support Plan in Jiangxi Province

**Correspondence to: Prof. Jun Xiong**, Acupuncture and Rehabilitation Department, The Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine, Nanchang 330006, China; Key Laboratory of Heat-sensitive Moxibustion, State Administration of Traditional Chinese Medicine of People's Republic of China, Nanchang 330006, China; Acupoint Sensibility Laboratory, State Administration of Traditional Chinese Medicine of People's Republic of China, Nanchang 330006, China. xiongjun196071@yahoo.com.cn
**Telephone**: 86-791-6362653
**Accepted**: March 20, 2012

## Abstract

**OBJECTIVE**: To assess the efficacy and safety of heat-sensitive moxibustion in the treatment of lumbar disc herniation (LDH).

**METHODS**: Randomized controlled trials (RCTs) involving heat-sensitive moxibustion in the treatment of LDH were retrieved from the Chinese Biological Medical Literature database (1978-20011), Weipu database (1989-2011), Wanfang digital journal (1998-2011), China National Knowledge Internet (1979-2011), PubMed (1966-2011), EMBASE (1980-2011), and Cochrane Library (Issue 1, 2011). Hand-search of the relevant journals from the Library of Jiangxi University of Traditional Chinese Medicine was also adopted for the collection of data. Data were extracted and evaluated by two reviewers independently with a specially designed extraction form. The Cochrane Collaboration's RevMan 5.0.20 software was used for data analyses.

**RESULTS**: A total of 6 trials involving 580 patients were included. Meta-analysis showed that the total effectiveness rate in the heat-sensitive moxibustion group was significantly different when compared with conventional moxibustion [*RR*=1.19, 95% *CI* [1.06, 1.33)] and diclofenac sodium [*RR*=1.47, 95% *CI* [1.17, 1.85)], but similar to that of acupuncture. The cure rate in the heat-sensitive moxibustion group was significantly different when compared with conventional moxibustion [*RR*=1.58, 95% *CI* (1.04, 2.40)] and diclofenac sodium [*RR*=1.91, 95% *CI* (1.01, 3.60)], but similar with that of acupuncture. In terms of the Japanese Orthopaedic Association scores, significant differences were noted in subjective indices, objective indices, and daily life subscales. Two trials reported that there were no adverse events over the duration of treatment.

**CONCLUSION**: Compared with conventional moxibustion, acupuncture, and diclofenac sodium, heat-sensitive moxibustion in the treatment of LDH is superior in efficacy. Further large-scale trials are required to define the role of heat-sensitive moxibustion in the treatment of this disease.

**Key words**: Moxibustion; Intervertebral disk displacement; Randomized controlled trial; Meta-analysis

## INTRODUCTION

Lumbar disc herniation (LDH) is a clinical syndrome resulting from lumbar intervertebral disc degeneration, with rupture of the fibrous ring and protrusion of the nucleus pulposus, so that the nerve roots and cauda equina are impinged and stimulated.[1] Since Mixter and Barr found that LDH could cause low back pain and sciatica in 1934, much research has been done to obtain a clearer understanding of it.[2] According to recent statistical data, LDH patients constitute about 15% of the outpatients and about 40% of the inpatients with low back and leg pain. It has been reported that about 2 million people suffer from it in the United States each year. About 80% of the adults in China have low back and leg pain, and about 20% of them are diagnosed with LDH.[3] As the rhythm of life speeds up, the incidence of LDH increases year by year, and it seriously influences the health and quality of life of many people.

The pathogenesis of LDH derives from mechanical compression, chemical radiculoneuritis, and autoimmunity.[4] All these are thought to be the effect of anatomical factors combined with external physical factors. At present, the clinical treatment of LDH involves mostly conservative treatment, with which 80% of the patients are cured or relieved. These measures include bed rest, traction, physiotherapy, massage, epidural injection with adrenocortical hormone, and chemical dissolving of nucleus pulposus, etc. Researchers focus their attention on the efficacy and safety of these interventions to seek treatments that are non-invasive and minimal in side effects.

Acupuncture is widely used for LDH as a "green" treatment. Heat-sensitive moxibustion is popular with more and more people in recent years because of its significant clinical efficacy and safety.[5-7] There are many relevant clinical trials on heat-sensitive moxibustion in the treatment of LDH at home and abroad. However, relevant evidence-based medical evaluation is insufficient. Therefore, this study aimed to evaluate its efficacy and safety with meta-analysis.

## MATERIALS AND METHODS

### *Inclusion criteria*

Study characteristics: Randomized controlled trial (RCT), regardless of blinding. Conducted in Chinese and English.

### *Study subjects*

The patient's age, gender, case from any source. Having a clear diagnosis standard.

### *Intervention*

Application of heat-sensitive moxibustion in the trial group. Not limited in the control groups.

### *Outcome measures*

Japanese Orthopaedic Association (JOA) score, the effectiveness rate, cure rate, recurrence rate, and incidence of adverse events.

### *Exclusion criteria*

Duplicates of studies were excluded.

### *Search strategy*

Electronic retrieval was used. The databases were the Chinese Biological Medical Literature database (CBM, 1979-2011), China National Knowledge Internet (CNKI, 1979-2011), Weipu database (VIP, 1989-2011), and Wanfang digital journal (WF, 1998-2011). Online databases from abroad were PubMed (1966-2011), EMBASE (1980-2011), and the Cochrane Library (Issue 1, 2011). If the full text could not be obtained, a manual retrieval from the library of the Jiangxi University of Traditional Chinese Medicine was adopted. All searches ended at June 30, 2011.

### *Evaluation method*

Data extraction: Two independent evaluators read the abstract of each text. After removing those trials which did not conform to the inclusion criteria, the evaluators read the full text to determine whether it would be included. They double-checked the evaluation results by exchanging with each other. Discussion would be held or the decision would be made by the third decision maker when there were disagreements on inclusion of a certain trial or not.

### *Quality evaluation*

According to the quality criteria in the Cochrane Review Handbook 5.0 recommendation, the bias risk assessment tool included six aspects). 1) random distribution methods; 2) allocation concealment; 3) blinding for participants, practitioners, and outcome assessors; 4) complete outcome data; 5) selective outcome reporting data; 6) other bias sources. Each of the research results would be judged explicitly by these criteria by using: Yes (low risk of bias), No (high risk of bias), or Unclear (uncertain risk of bias). Criteria 1), 2), and 5) were used to evaluate the bias risk of each included study, and the other three criteria were used to evaluate the research results according to the different assessments, emphasizing the different degrees of the influence of bias on study results from the same paper. Two decision makers double-checked the evaluation results by exchanging with each other. The eligibility of the tri-

als would be assessed by discussion to resolve disagreements on inclusion or not, or the decision would be made by the third decision maker.

Data analysis: A meta-analysis was done by using Review Manager (Version 5.0.20) provided by Cochrane network. The studies for inclusion were determined by inspection for heterogeneity and $P<0.1$ was taken as the inspection standard. If there was no heterogeneity among the trials, a fixed effect model would be applied in the meta-analysis. If there was heterogeneity among the trials, the sources of heterogeneity would be determined. If there was no clinical or methodological heterogeneity, a random effect model would be used in the meta-analysis. The dichotomous data were summarized as relative risk (RR). The continuous data were reported as weighted mean difference (WMD) or standard mean difference (SMD). Their effect sizes were expressed as 95% confidence intervals throughout, and $P\leq0.05$ would be thought a difference with statistical significance. If obvious clinical heterogeneity existed in the trials, a descriptive analysis would be given. If necessary, the sensitivity analysis would be used to check the stability of the test results.

## RESULTS

### *Search result*

An initial screening yielded 181 potentially relevant citations in accordance with the search strategy. According to the inclusion criteria, based on the titles and abstracts, 175 articles were excluded. Ultimately, 6 studies, including 580 patients, were included for analysis.

### *Characteristics of the trials included*

Study characteristics: All trials were single center, randomized, and parallel group (treatment and control) trials.

Study object: Participants were from outpatient services and inpatient departments. Two trials[8,11] used the Clinical Disease Diagnosis Standard and National Physical Examination Standard. Two trials[9,10] used the National Diagnosis And Curative Standard of Disease And Syndrome of Traditional Chinese Medicine promulgated by the State Administration of Traditional Chinese Medicine in 1994. The rest of the trials used different diagnosis standards. Only three trials[9,10,13] reported the inclusion and exclusion standards.

Intervention: Heat-sensitive moxibustion was used in the treatment groups. There was a control group using traditional suspend moxibustion in three trials.[8,9,13] Two trials[11,12] used acupuncture for the control groups. Only one trial[10] used Western medicine for the control group.

Outcome measures: All the trials used the effectiveness and cure rates as outcome measures, but the sources of curative standard were different. Three trials[9-11] used the 1994 National Diagnosis And Curative Standard of Disease And Syndrome of Traditional Chinese Medicine promulgated by the State Administration of Traditional Chinese Medicine, while others used a self-made standard. Only one trial[11] used the JOA score.

Methodological Quality: Most trials were not of high quality (Figure 1). Of the six trials, two[9,10] used a computer to produce the randomization sequence; one[13] used a random table method; the other trials only referred to randomization without specifying a method. None of the trials reported allocation concealment. Only one trial[12] used single blinding. Two trials[9,10] reported missed cases, but both of them did not use the inten-

Table 1 Characteristics of the trials included

| Included study | Participants | | Duration | Intervention | | Outcome measures |
|---|---|---|---|---|---|---|
| | Treated group | Control group | | Treated group | Control group | |
| Xie YF[8] 2010 | 40 | 26 | 10 d | Heat-sensitive moxibustion | Traditional suspend moxibustion | Efficient rate, cure rate |
| Tang FY[9] 2009a | 60 | 60 | 7 d | Heat-sensitive moxibustion | Traditional suspend moxibustion | Efficient rate, cure rate, recurrence rate |
| Tang FY[10] 2009b | 60 | 60 | 7 d | Heat-sensitive moxibustion | Diclofenac sodium | Efficient rate, cure rate, recurrence rate |
| He JP[11] 2008 | 37 | 37 | 20 d | Heat-sensitive moxibustion | Acupuncture | Efficient rate, cure rate |
| Kang MF[12] 2009 | 35 | 35 | 20 d | Heat-sensitive moxibustion | Acupuncture | Joa score, efficient rate, cure rate, |
| Tang FY[13] 2009b | 60 | 60 | 14 d | Heat-sensitive moxibustion | Traditional suspend moxibustion | Efficient rate, cure rate, recurrence rate |

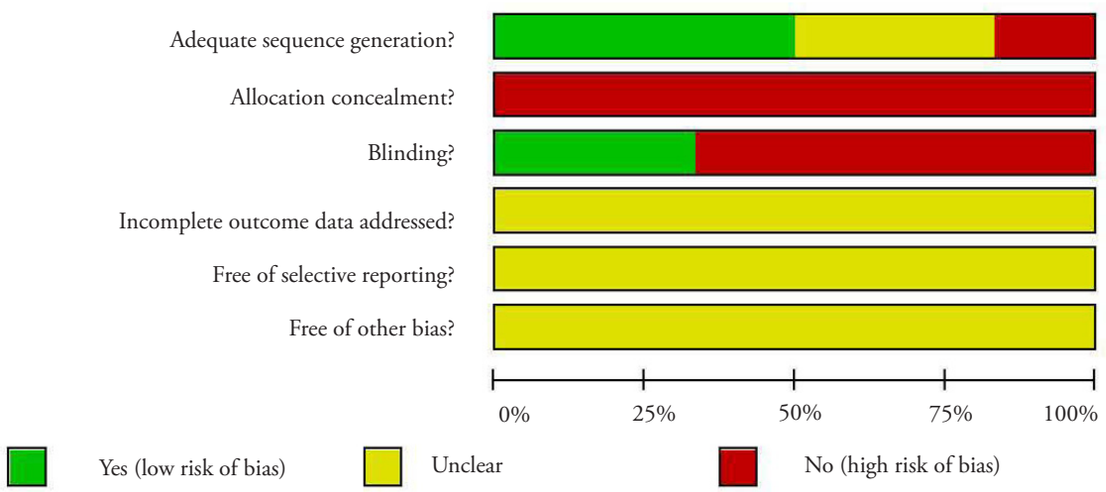


Figure 1 Analysis on the risk of bias of included trials

tion-to-treat analysis (ITT). Another four trials[9-11,13] had a follow-up report. None of the papers described the baseline characteristics of the subjects, except for one trial;[11] the others only mentioned baseline characteristics and comparability. See Figure 2 for the bias analysis on each trial.

***Efficient rate***

Three trials[9-11] in this analysis used the 1994 National Diagnosis And Curative Standard of Disease And Syndrome of Traditional Chinese Medicine for effectiveness rate calculations. As illustrated in Figure 3, subgroup analysis was carried out. Heat-sensitive moxibustion vs traditional suspend moxibustion: in two trials,[9,13] the subgroup analysis showed a significant statistical difference [*RR*=1.19, 95%*CI* (1.06, 1.33)]. Heat-sensitive moxibustion vs diclofenac sodium: in one trial,[10] the subgroup analysis showed a significant statistical difference [*RR*=1.47, 95%*CI* (1.17, 1.85)]. Heat-sensitive moxibustion vs acupuncture: in one trial,[11] the subgroup analysis showed no significant statistical difference [*RR*=1.14, 95%*CI* (0.97, 1.35)].

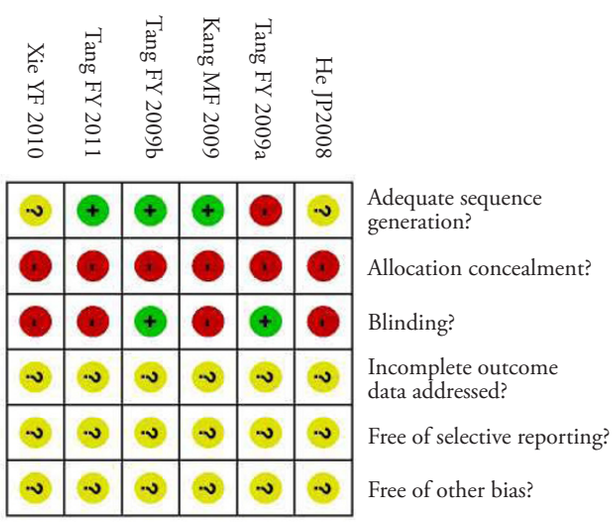


Figure 2 Summary of the risk of bias of trials included

***Cure rate***

Three trials[9-11] in this analysis used the 1994 National Diagnosis And Curative Standard of Disease And Syndrome of Traditional Chinese Medicine for cure rate calculations.As illustrated in Figure 4, subgroup analysis was carried out.

Heat-sensitive moxibustion vs traditional suspend moxibustion: in two trials[9,13],the subgroup analysis showed no significant statistical difference [*RR*=1.58, 95% *CI* (1.04,2.40)]. Heat-sensitive moxibustion vs diclofenac sodium: in one trial,[10] the subgroup analysis showed a significant statistical difference [*RR*=1.91,95%*CI* (1.01, 3.60)]. Heat-sensitive moxibustion vs acupuncture: in one trial,[11] the subgroup analysis showed a significant statistical difference [*RR*=1.46,95%*CI* (1.08,1.98)].

***JOA score***

In the only trial[12] included in this analysis using this measure, the subgroup analysis showed that there were significant statistical differences regarding subjective indicator, objective indicator, and daily living skills subscales [*RR*=0.56, 95%*CI* (0.11, 1.01)], [*RR*=1.20, 95% *CI* (0.53, 1.87)], [*RR*=1.26, 95%*CI* (0.36, 2.16)].

***Recurrence rate***

In the two trials[9,10] included in this analysis, the outcome was measured six months after treatment.

The subgroup analysis showed that there were significant statistical differences [*RR*=0.42, 95% *CI* (0.26, 0.65), *RR*=0.33, 95%*CI* (0.13, 0.87)].

***Safety assessment***

Two trials[9,10] reported that for the duration of treatment there were no adverse reactions presented. Others had no descriptions of adverse reactions.

## DISCUSSION

In our research, we included six randomized controlled trials, a total of 580 patients. Most of these trials were

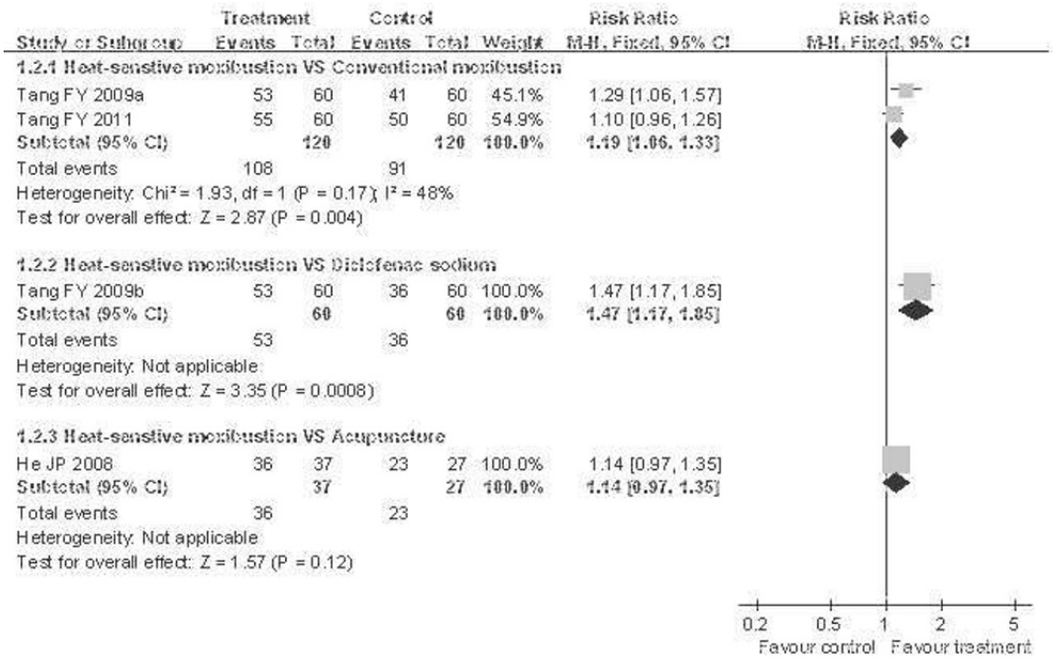


Figure 3 Subgroup analysis of the effectiveness rate

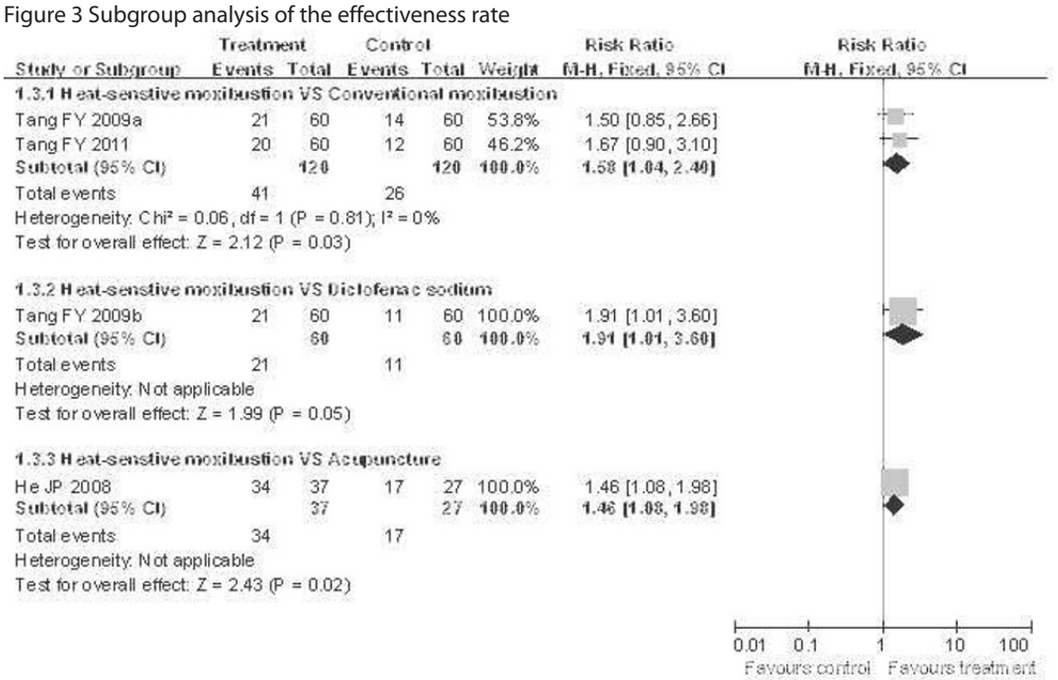


Figure 4 Subgroup analysis of the cure rate

of small samples and their methodological quality was not high. Only three trials described their specific randomization methods, whilst the rest mentioned randomization but without a description of the randomization method. None of the trials described the implementation of allocation concealment, so this might have caused selection bias. None of the trials detailed the subject baseline characteristics, the lack of which might also conceal selection bias. In short, the low quality of the trials might lead to clinical heterogeneity and bias of the results. Care is needed in the evaluation of these results in clinical practice.

This paper aimed to evaluate the clinical efficacy and safety of heat-sensitive moxibustion. Based on the different control groups, subgroup analyses were used. Results showed that the curative and effective rates of heat-sensitive moxibustion were better than those of the Western medicine diclofenac sodium. Compared with traditional moxibustion and acupuncture, heat-sensitive moxibustion had a therapeutic advantage, but the conclusion should be confirmed with the observation of more samples.

In conclusion, heat-sensitive moxibustion has an advantage in therapeutic effect for LDH. More high quality randomized controlled trials are needed for further confirmation. The suggestion is that more strict designs should be made and larger sample sizes used to carry out multicentric randomized controlled trials to evaluate the efficacy and safety of heat-sensitive moxibustion in the treatment of LDH.[14]

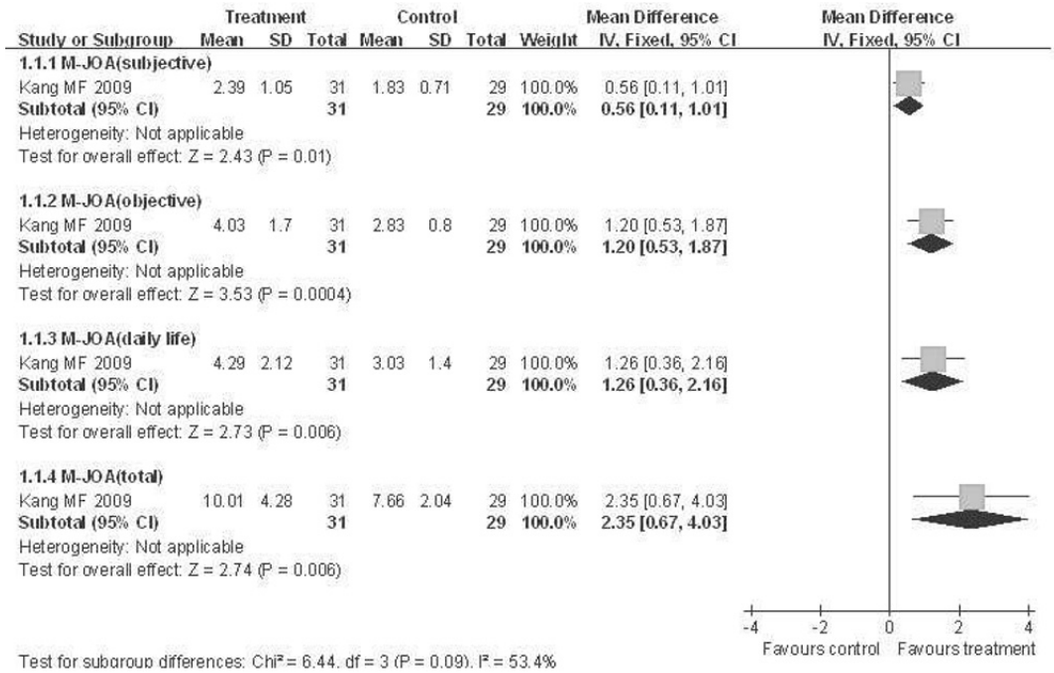


Figure 5 Subgroup analysis of the JOA score

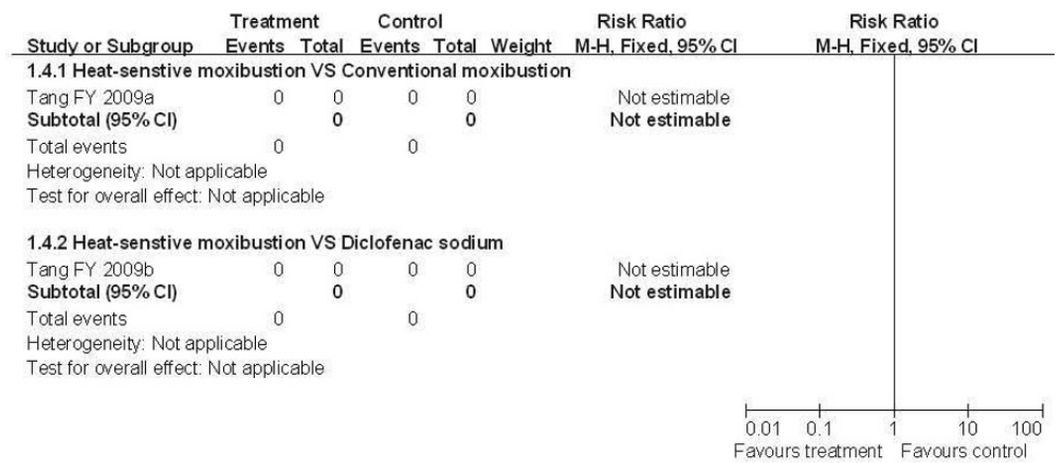


Figure 6 Subgroup analysis of the recurrence rate

## REFFERENCES


1 **Wu ZS**, Zhen S, Wang TY, Ye SB. Surgery. 5th edition, Beijing: Ren Min Wei Sheng Chu Ban She 2003: 875-878.

2 **Zhu RF**, Sun SX. Research progress of minimally invasive surgical treatment for lumbar intervertebral disc herniation of. Zhongguo Jiao Xing Wai Ke Za Zhi 2004; 12(17): 1334-1336.

3 **Wu XW**, Chen Y. The cause of lumbar intervertebral disc herniation and nursing. China Medical Guidelines 2008; 24 (6): 401-402.

4 **Pan HJ**. Biomechanics analysis on lumbar intervertebral nucleus pulposus outstanding disease. China Journal Of Sports Medicine 2002; 21(2): 138-140.

5 **Chen RX**, Kang MF. The clinical application of heat-sensitive moxibustion. Chinese Acupuncture And Moxibustion 2007; 27(3): l99-202.

6 **Chen RX**, Kang MF. The heat-sensitive acupoints and their clinical significance. Journal of Traditional Chinese Medicine 2006; 47(12): 905-906.

7 **Chen RX**, Kang MF. The key of moxibustion is *Qi* arrival. Chinese Acupuncture And Moxibusiton 2008; 28(1): 44-46.

8 **Xie YF**, Ruan YD, Ning XJ. The heat-sensitive moxibustion terat intervertebral disc in 40 patients. Chinese Folk Therapy 2010; 18(9): 11.

9 **Tang FY**, Huang CJ, Chen RX. Xu M, Liu BX, Liang Z. Curative effect observation for heat-sensitive moxibustion in the treatment of lumbar intervertebral disc. Chinese Acupuncture And Moxibusiton 2009; 29(5): 382-384.

10 **Tang FY**, Huang CJ, Chen RX. Xu M, Liu BX, Liang Z. Clinical research on heat-sensitive moxibustion in the treatment of lumbar intervertebral disc. Journal of Jiangxi Institute Of Traditional Chinese Medicine 2009; 21(1): 25-27.

11 **He JP**, Huang YH. Clinical research on heat-sensitive moxibustion in the treatment of lumbar intervertebral disc. Asia-Pacific Traditional Medicine 2008; 4(12): 69-70.

12 **Kang MF**, Ren YL. 31 cases of heat-sensitive moxibustion and acupuncture in the treatment of lumbar intervertebral disc. Zhejiang Journal Of Traditional Chinese Medicine 2009; 44(4): 289-290.

13 **Tang FY**, Liang Z, Wang J, Liang DB, Tang HW. Clinical observation on heat-sensitive moxibustion in the treatment of lumbar intervertebral disc. Jiangxi Journal Of Traditional Chinese Medicine 2011; 42(2): 65-67.

14 **Chen RX**, Kang MF. A new type of disease reflex point-heat-sensitive point and its clinical implications. Journal of Jiangxi Institute Of Traditional Chinese Medicine 2006; 26 (2):29-30.