

Blade needle therapy versus conventional acupuncture for knee osteoarthritis A meta-analysis

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Abstract

Background: This study investigated the hypothesis that the efficacy of blade needle therapy for the treatment of knee osteoarthritis (KOA) is superior to that of conventional acupuncture. In addition, the efficacy of blade needle therapy versus conventional acupuncture for the treatment of KOA was analyzed in a meta-analysis.

Methods: Randomized controlled trials (RCTs) of blade needle therapy and conventional acupuncture for treating KOA were retrieved from the electronic databases CNKL, Wanfang, VIP, PubMed, EMBASE and the Cochrane Library from the commencement of each database to July of 2021. Data were extracted and evaluated by 2 reviewers independently. RevMan 5.3 software was used to conduct the meta-analysis after the studies were evaluated.

Results: A total of 11 RCTs were included, all from China, involving 1142 patients. The meta-analysis results showed that the effective rate of the blade needle group was better than that of the conventional acupuncture group (OR = 3.61, 95% Cl [2.56–5.10], P < .00001).

Conclusion: The efficacy of blade needle treatment for KOA is superior to that of conventional acupuncture, but more high-quality studies are needed for future validation due to the low proportion of high-quality studies included and the possible bias factor.

Abbreviations: CI = confidence interval, KOA = knee osteoarthritis, NSAIDs = nonsteroidal antiinflammatory drugs, RCTs = randomized controlled trial, SMD = STD mean difference, TCM = traditional Chinese medicine, VAS = visual analog scale.

Keywords: blade needle, conventional acupuncture, knee osteoarthritis, meta-analysis

1. Introduction

Knee osteoarthritis (KOA) is a common and complex disease affecting approximately 10% of the global population over 60 years of age.^[1] In Europe, approximately 25% of people aged over 55 have a previous record of knee pain, and a quarter of patients may become disabled as a result.^[2] Approximately 37% of people over the age of 60 in the United States have KOA.^[3] In China, the prevalence of KOA is nearly 50% in people above age 60, 53% of patients are disabled and live with difficulty, and more than 65% of patients have recurrent attacks that persist, seriously affecting their survival quality.^[4–6] However, the treatment outcome is hardly satisfactory for patients or medical practitioners and has become an urgent problem for clinicians.^[7] Neither nonsteroidal anti-inflammatory drugs (NSAIDs) nor intra-articular injections of sodium glacial acetic acid for KOA

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seem to cause adverse effects such as gastric bleeding, peptic ulcers and allergies.^[8,9] Although surgery is the last resort, it is often ineffective and associated with numerous surgical complications^[10–15]; therefore, the search for a more effective treatment is one of the current hot topics of research in the treatment of KOA. Conventional acupuncture therapy is one of the characteristic therapies of traditional Chinese medicine (TCM) osteopathy, which not only facilitates the reduction of inflammation but also promotes blood circulation in local tissues.^[16] In recent years, conventional acupuncture therapy has been extensively used clinically for its safety and effectiveness, and reports on acupotomy and acupuncture for KOA treatment are increasing.^[17-21] Acupotomy not only loosens and peels away adherent tissues but also stimulates acupoints to produce a meridian sensing effect.^[22] Acupuncture treatment for KOA reduces pain and morning stiffness in the diseased area, slows degenerative

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Ethics statement: This study is a meta-analysis, which is mainly a process of collecting data for analysis using statistical software, and does not involve human or animal experimentation, and there are no ethical aspects involved in this study.

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changes in articular cartilage and restores knee function,^[23,24] which improves the efficacy and shortens the course of treatment.^[25] Recently, a new type of external TCM blade needle that incorporates the characteristics of acupotomy and acupuncture has been applied.^[26–28] Studies on the efficacy of blade needle treatment for KOA have been increasing, but a review of the literature has not provided a systematic and objective evaluation of the efficacy of blade needle treatment for KOA. Therefore, in this study, an objective and credible meta-analysis was conducted to provide a reliable basis for the clinical treatment of KOA by reviewing a large number of relevant studies and to report the status of the use of blade needle in clinical practice and the problems that exist. The analysis is as follows.

2. Materials and Methods

Statement: This study is a meta-analysis, which is primarily a process of collecting data and analyzing them with statistical software to draw conclusions. This study is not about human or animal experiments and this study does not involve ethical issues.

2.1. Search strategy

The search databases included the China National Knowledge Infrastructure, Wanfang Data, VIP, PubMed, EMBASE, Cochrane Library, etc. All the databases were searched from their origin to July 25, 2021, and only studies in Chinese or English were searched.

The Chinese database search formula was as follows: ("Knee Osteoarthritis" OR "Knee Osteoarthritides" OR "Osteoarthritis of Knee" OR "Osteoarthritis of the Knee" AND ("Blade needle" OR "Edge needle" OR "Cutting needle" OR "needle-knife" OR "acupotomology" OR "acupotome" OR "acupotomy") AND ("Random"). The English database search formula was as follows: ("Knee Osteoarthritis" OR "Knee Osteoarthritides" OR "Osteoarthritis of Knee" OR "Osteoarthritis of the Knee") AND ("Blade needle" OR "Edge needle" OR "Cutting needle" OR "needle-knife" OR "acupotomology" OR "acupotome" OR "acupotomy") AND ("Random").

2.2. Literature inclusion criteria

(1) Study type: Randomized controlled trials (RCTs) or semirandomized controlled trials of blade needle versus conventional acupuncture in the treatment of KOA, limited to Chinese and English, were collected. (2) Study population: Studies of patients with KOA, regardless of the source, wherein patient age and sex and clear and recognized diagnostic criteria were reported were included. (3) Interventions: Blade needle therapy was performed in the treatment group (not combined with other therapies), and conventional acupuncture was performed in the control group (excluding electroacupuncture); studies of combinations of other therapies were excluded. (4) Outcome index: Studies reporting a treatment efficiency outcome were included.

2.3. Literature exclusion criteria

The exclusion criteria were as follows: (1) nonRCTs, (2) studies with unclear or nonaccepted diagnostic criteria or efficacy criteria, (3) studies that included other therapies, such as manipulation, moxibustion, and drugs, (4) animal experimental studies, and (5) theoretical and review literature and repeatedly published literature.

2.4. Data extraction and literature quality evaluation

Two evaluators independently screened the literature and first read the title and abstract of the literature to initially exclude those studies that did not meet the inclusion criteria; if they could not judge, they read the full text to further judge; if 2 independent evaluators disagreed on the inclusion or noninclusion of the literature and the quality score, the 2 evaluators sought a mutually agreeable third evaluator to discuss and negotiate a conclusion.

The included literature was evaluated using the risk of bias assessment tool recommended by the Cochrane Handbook for Systematic Reviews, which includes seven entries: generation of randomized sequences; allocation concealment of randomized protocols; blinding of study subjects and performers; blinding of outcome evaluators; completeness of outcome data; selective reporting; and other sources of bias. Each entry was classified into 3 levels: low risk, unclear risk, and high risk of bias.

The main information extracted included (1) information related to the included studies, such as the title of the literature, first author, and time of publication; (2) information related to the study population, including number of patients, age, follow-up time, and intervention modality; and (3) each outcome indicator of interest.

2.5. Statistical analysis of data

RevMan 5.3 software provided by the Cochrane Collaboration Network was used for the analysis. Due to the different data units reported in the original literature, continuous variables were used using standardized mean difference (SMD) representation, and estimates and 95% confidence intervals (CIs) are given for each effect indicator.

The χ^2 test and Higgins I² test were used to test for heterogeneity among the outcomes, and if I2 \leq 50%, a fixed-effects model was used for analysis; if 50%<I2 \leq 75%, a random-effects model was used for analysis; I2 > 75% was not included in the combined analysis.

If > 10 studies were included, Egger test and funnel plots were used to detect publication bias. P > 0.05 indicates nonsignificant publication bias, and P < 0.05 indicates publication bias. The test level for the meta-analysis was set at a = 0.05.

3. Results

A total of 605 documents were retrieved from various databases based on the search strategy. After checking and reading the titles and abstracts, 478 studies were initially screened. After reading the full text, studies that did not meet the inclusion criteria were excluded, and 11 articles remained for inclusion in the meta-analysis,^[29-39] all of which were published in Chinese. The literature screening process is shown in Figure 1. Eleven publications involving a total of 1142 KOA patients were included, with 571 in the trial group and 571 in the control group. In the test group, 8 were treated with a blade needle, 2 with a curved blade needle, and 1 with an oblique circular blade needle. In the control group, all were treated with conventional acupuncture. The basic characteristics of the specific included studies are shown in Table 1. The risk of bias for the included trials is summarized in Figures 2 and 3.

The clinical efficacy of the blade needle group was analyzed in comparison with that of the conventional acupuncture group, and the results of the heterogeneity test were $\chi^2 = 6.24$, P = .79, I2 = 0%. This finding indicates that there was no significant heterogeneity between the studies using a fixed effects model. The results of the meta-analysis showed statistically significant differences in efficacy between the blade needle group and the conventional acupuncture group (OR = 3.61, 95% CI [2.56, 5.10], Z = 7.29, P < .00001). Blade acupuncture had significantly higher efficacy than conventional acupuncture for the treatment of KOA (Fig. 4). The clinical efficacy funnel plot showed poor symmetry, suggesting possible publication bias in the literature included in the analysis (Fig. 5).

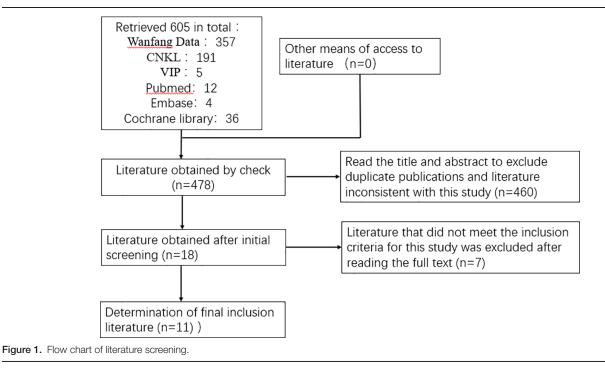


Table 1

Characteristics of included articles.

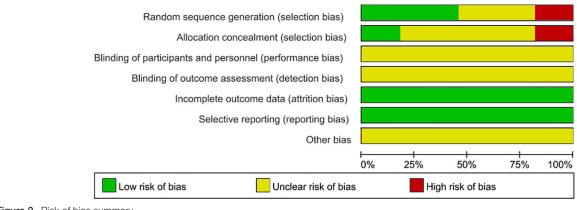
| | Published time | The number of cases | | | | | |
|----------------|----------------|-----------------------|--------------------------------|-----------------------|-----------------------------------|---------------------|---------------|
| Name | | Blade needle group | Conventional acupuncture group | Blade needle group | Conventional acupuncture group | Period of treatment | Lost/ quit |
| Baidong Xiang | 2019 | 36 | 36 | Blade needle | Conventional acupuncture | 10 days | No |
| Chunxiang Chen | 2018 | 58 | 58 | Blade needle | Conventional acupuncture | 3 weeks | No |
| Jun Duan | 2014 | 30 | 30 | Blade needle | Conventional acupuncture | 3 weeks | No |
| Leigang Zheng | 2014 | 128 | 130 | Blade needle | Conventional acupuncture | 2 weeks | Yes |
| Liangjun Li | 2013 | 50 | 50 | Blade needle | Conventional acupuncture | 3 weeks | No |
| Linhai Zhang | 2018 | 34 | 34 | Blade needle | Conventional acupuncture | 4 weeks | No |
| Manhu Yang | 2020 | 31 | 31 | Blade needle | Conventional acupuncture | 3 weeks | No |
| Mingging Wu | 2011 | 50 | 50 | Blade needle | Conventional acupuncture | 3 weeks | No |
| Shuaigang Du | 2018 | 74 | 72 | Blade needle | Conventional acupuncture | 4 weeks | Yes |
| Yunfei Xu | 2019 | 50 | 50 | Blade needle | Conventional acupuncture | 2 weeks | No |
| Yunsheng Huang | 2015 | 30 | 30 | Blade needle | Conventional acupuncture | 2 weeks | Yes |

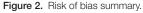
To further test whether there was publication bias, Begg and Egger tests were performed. The result of the Begg method was nonsignificant (P = .350), suggesting no significant publication bias, as shown in Figure 6. The result of the Egger method was significant (P < .001), suggesting the existence of publication bias, as shown in Figure 7. The publication bias may be due to the fact that articles with negative results are not easy to publish, because the literature was all published in Chinese, which is subject to language bias, and because fewer study subjects were included in some of the articles.

4. Discussion

For this meta-analysis, the screening process and criteria were developed by searching domestic and international medical databases and strictly following the PRISMA principles. Ultimately, 11 RCTs involving 1142 patients were included in this study; a total of 571 patients were included in the blade needle group, with 510 effective cases of blade needle therapy, and 571 patients were included in the conventional acupuncture group, with 413 effective cases of conventional acupuncture. Meta-analysis showed OR = 3.61, 95% CI [2.56–5.10], P < .00001, indicating that blade needle therapy is better than conventional acupuncture for the treatment of KOA (P < .05). Altogether, the findings suggest that blade needle treatment is preferred in the treatment of KOA in clinical practice.

Currently, there is no consensus on the best treatment for KOA, and there is no curative treatment at home or abroad. Western medical treatment mainly includes nonsteroidal antiinflammatory drugs, antirheumatic drugs, glucocorticoids, intraarticular injection drugs and surgical treatment.^[40] Although these treatments have achieved good clinical results, adverse effects such as gastrointestinal reactions and liver and kidney injury should not be ignored. Traditional Chinese medicine treatments for knee osteoarthritis mainly include internal treatment, external treatment, acupuncture therapy, tui-na, etc. Chinese medicine treatment not only relieves clinical symptoms and improve the function of the knee joint of patients but also delays the destruction of joint cartilage and prevents the rapid progression of knee osteoarthritis.^[41] To date, blade needle therapy has been widely used in clinical practice for the treatment of knee arthropathies, degenerative spinal diseases,





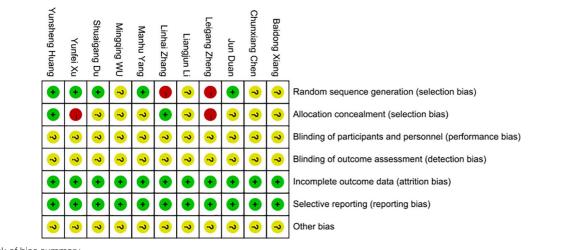
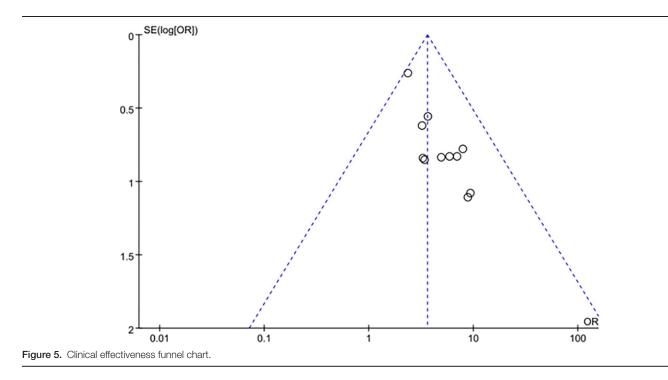


Figure 3. Risk of bias summary.

| | Blade ne | | Conventional acu | | | Odds Ratio | Odds Ratio |
|-----------------------------------|--------------|-----------|------------------|-------|--------|--------------------|--|
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H, Fixed, 95% C | I M-H, Fixed, 95% Cl |
| Baidong Xiang | 34 | 36 | 30 | 36 | 4.5% | 3.40 [0.64, 18.13] | |
| Chunxiang Chen | 53 | 58 | 43 | 58 | 10.0% | 3.70 [1.24, 10.99] | |
| Jun Duan | 28 | 30 | 20 | 30 | 3.6% | 7.00 [1.38, 35.48] | |
| Leigang Zheng | 90 | 128 | 65 | 130 | 51.9% | 2.37 [1.42, 3.95] | - ∎ - |
| Liangjun Li | 48 | 50 | 44 | 50 | 4.8% | 3.27 [0.63, 17.07] | |
| Linhai Zhang | 32 | 34 | 26 | 34 | 4.1% | 4.92 [0.96, 25.22] | |
| Manhu Yang | 29 | 31 | 22 | 31 | 3.8% | 5.93 [1.16, 30.25] | |
| Mingqing WU | 46 | 50 | 39 | 50 | 8.5% | 3.24 [0.96, 11.00] | |
| Shuaigang Du | 72 | 74 | 59 | 72 | 4.4% | 7.93 [1.72, 36.56] | |
| Yunfei Xu | 49 | 50 | 42 | 50 | 2.3% | 9.33 [1.12, 77.70] | |
| Yunsheng Huang | 29 | 30 | 23 | 30 | 2.1% | 8.83 [1.01, 76.96] | |
| Total (95% CI) | | 571 | | 571 | 100.0% | 3.61 [2.56, 5.10] | • |
| Total events | 510 | | 413 | | | | |
| Heterogeneity: Chi ² = | 6.24, df = 1 | 0 (P = 0 | .79); l² = 0% | | | | 0.01 0.1 1 10 100 |
| Test for overall effect: | Z = 7.29 (F | o < 0.000 | 01) | | | | 0.01 0.1 1 10 100 Conventional acupuncture Blade needle |

frozen shoulder, muscle strain and cutaneous nerve entrapment and has achieved certain efficacy.^[42] Blade needles cut a small amount of tense muscle fibers or fascia to reduce the tension stress of the tissue, decrease the abnormal adhesions between the tissue muscle fascia, and mitigate the compression effect of the diseased tissue on blood vessels, nerve bundles, and bone fiber canals. Compared with conventional acupuncture treatment, the cutting and release action of blade needle therapy is more advantageous for improving joint pain and functional issues. Blade needle therapy is implemented under the guidance of meridian tendon theory in combination with information from Western medicine and taking into account the body's structural mechanics and anatomy, among other disciplines. Needles are placed through the point of meridian tendon lesions to unblock peeling, release adhesions, restore the mechanical balance of the joint, improve blood flow and lymphatic circulation in the joint, and promote local tissue metabolism, thereby correcting the joint and making it more



Begg's funnel plot with pseudo 95% confidence limits

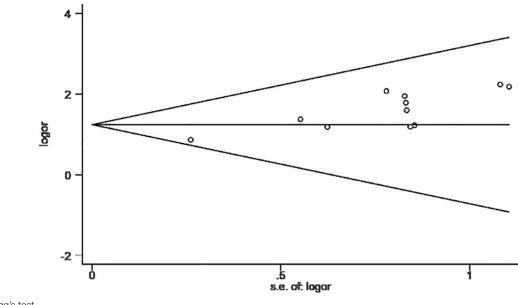
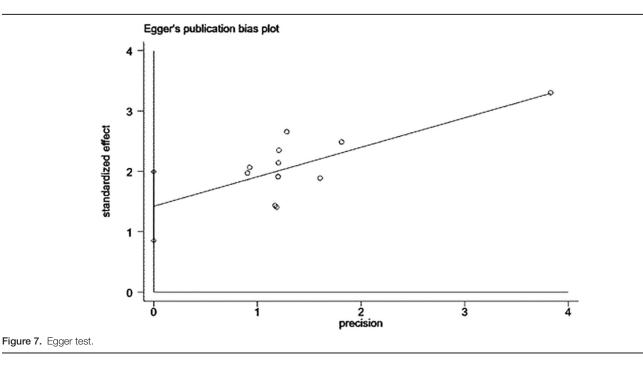


Figure 6. Begg's test.

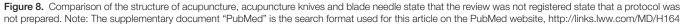
tender with the goals of improving joint pain, movement and function and ensuring the continuity of the therapeutic effect.^[43] As a minimally invasive medical technique, this therapy presents a unique approach to improving the balance of forces within the knee joint and is effective at relieving clinical symptoms. A comparative diagram of the structures of acupotomy, acupuncture and blade needle therapy is shown in Figure 8.

Through this study, we expect to provide some evidence for the clinical effectiveness of blade needle in the treatment of KOA, and to dispel the misconceptions or fears of the public about blade needle. Because the body and blade of the blade needle are smaller than those used for acupuncture,^[44] the blade needle causes less trauma to the patient during treatment and is less painful and easier to operate, and the standardized approach to blade needle therapy can prevent the dissociation of nerves and tendons and is easy to master^[45], while it is more acceptable to patients and more clinically developed and popular because it is less expensive than surgical and other treatments.

However, only 5 of the 11 articles included in this study mentioned a specific randomized method, and none of the articles mentioned blinding or provided information on the application procedure, which might be due to a lack of attention to these details. In terms of adverse events, none of the studies reported whether adverse reactions were observed, and the safety of blade needle treatment for KOA has not been evaluated. It is hoped that more details on its safety will be reported in future RCTs. The inclusion of literature in Chinese and the difficulty of publishing negative trials may have resulted in some publication bias.







As all the included trials measured efficacy only at the end of treatment, no comparison can yet be made regarding the long-term efficacy of blade needle therapy and conventional acupuncture for KOA. There are also some limitations to this study. The observation indicators and evaluation methods were not uniform across the studies, so it was impossible to conduct meta-analyses of the measures; thus, some specific indicators could not be analyzed. Additionally, the quality of the included literature was variable for the following reasons: (i) Three articles failed to mention diagnostic criteria. (ii) The descriptions of the randomization methods were not specific, with only 5 articles mentioning specific randomization methods. (iii) Allocation concealment was not mentioned in any of the studies, although it could be inferred from the original text in 2 studies. (iv) Considering the characteristics of the blade needle treatment itself, the blinding of patients as well as implementers could not be achieved; however, blinding could have been achieved in some of these sessions if the researcher had considered the experimental design more thoroughly. (v) Only 1 article mentioned follow-up, so the long-term efficacy of blade needle therapy for KOA remains unclear. (vi) The search included only a selection of commonly used databases in English and Chinese, which probably resulted in incomplete searches. However, through this study, it is expected that relevant investigators will be motivated to participate in more standardized training on clinical trial methodology, with the aim of reporting more relevant low-risk, high-quality studies in the future and providing stronger evidence for assessing the clinical efficacy of blade needle treatment for KOA.

This study found that few articles reported measures of the efficacy of blade needle therapy for KOA treatment, such as Visual Analogue Scale (VAS) scores, WOMAC scores, or joint mobility scores; therefore, it is difficult to standardize these studies. Moreover, the follow-up period for blade needle therapy for KOA treatment has been relatively short, so in the future, observational studies of its long-term efficacy need to be strengthened to further clarify the effectiveness of this therapy.

Author contributions

Xunlong Yin: coordinated planning, reviewed literature, screened data, did data analysis, wrote the article

Yuan Liu: rational division of labor, checking data, guiding writing the essay

Wu Liu: screening literature, checking data

Wei Liang: sifting literature, screening data, doing data analysis Qingyong Liang: screening literature, checking data

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