Systematic Review and Meta-Analysis

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Efficacy of ultrasound-guided acupotomy for knee osteoarthritis

A systematic review and meta-analysis of randomized controlled trials

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Abstract

Background: This systematic review aimed to evaluate the effectiveness and safety of ultrasound-guided acupotomy (UGAT) therapy in the treatment of patients with knee osteoarthritis (KOA).

Methods: We conducted online researches in the databases including PubMed, the Cochrane Library, EMBASE, China national knowledge infrastructure, China biomedical literature database, and Wan Fang data. All data were collected until January 1, 2022. Relevant randomized controlled trials on the effectiveness of UGAT for the treatment of KOA were included. Meta-analyses were carried out by RevMan 5.3 software. Evidence quality was evaluated by the grading of recommendations, assessment development, and evaluation.

Results: Eight studies including 543 participants were analyzed in this study. The pooled analysis indicated that UGAT was significantly more efficient than the control group in decreasing the visual analogue scale score (mean difference = −0.81, 95% confidence interval (CI) = [−1.15, −0.47], *P* < .00001, 8 studies), improving knee function on the Lysholm knee score (mean difference = 8.26, 95% CI = [1.56, 14.97], *P* = .02, 2 studies), and increasing clinical effective rate (relative risk = 1.14, 95% CI = [1.06, 1.23], *P* = .0005, 6 studies). For adverse events, UGAT was also associated with lower incidence of adverse event (odds ratio = 0.27, 95% CI = [0.12, 0.63], *P* = .002, 4 studies) compared to traditional acupotomy.

Conclusion: Current evidence suggested that UGAT therapy was effective and safe in the clinical treatments of KOA, thus could be suggested in the clinical managements of KOA. However, considering the unsatisfactory quality of the available trials, more large-scale, and better quality randomized controlled trials were recommend in future.

Abbreviations: AT = acupotomy, CI = confidence interval, EA = electroacupuncture, ER = effective rate, KOA = knee osteoarthritis, LKSS = Lysholm knee score, MA = manual acupuncture, MD = mean difference, OR = odds ratio, RCTs = randomized controlled trials, RR = relative risk, UGAT = ultrasound-guided acupotomy, VAS = visual analog scale.

Keywords: knee osteoarthritis, meta-analysis, systematic review, ultrasound-guided acupotomy

1. Introduction

Knee osteoarthritis (KOA) is a degenerative arthritis, primarily defined by the breakdown of joint cartilage and underlying bone. The clinical syndromes include knee pain, swelling, joint deformity, and disability.[1,2] According to previous studies, the incidence of KOA is more than 50% in people over 60 years old in China. Female presented higher incidence of KOA than male.[3] Approximately, 14 million people are suffering from KOA in the United States, and causing up to $420 million per year in the treatment of KOA.[4] With the increasing prevalence of obesity and the aging of the population, KOA constitutes a global burden and has become a serious public health problem.[5] The most common causes of KOA include aging, gender, obesity, skeletal muscle mass, menopausal status, genetics, and mechanical factors.[6] Currently, there are both surgical and conservative treatment options for KOA, with treatment aimed at pain relief, joint function protection, and improve life quality improvement.

SL and CL contributed equally to this work.

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The datasets generated during and/or analyzed during the current study are publicly available. All data generated or analyzed during this study are included in this published article [and its supplementary information files].

PROSPERO registration number: CRD42019145167.

This study will not involve personal information. The ethical approval will not be required. This systematic review will be disseminated electronically through a peer-reviewed journal or international conference presentations.

Supplemental Digital Content is available for this article.

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Common conservative treatment options include weight loss, knee strength training, nonsteroidal anti-inflammatory drugs administration, hyaluronic acid administration, acupuncture, moxibustion, extracorporeal shockwave, and acupotomy (AT).[7–10] Among these conservative therapies, AT, a new category of acupuncture combine the traditional acupuncture science with modern anatomy, modern surgical principles, and pathology theories.[11] The AT consists of a handle, cylindrical body, and flat head (Fig. 1). It can effectively eliminate adhesion, contracture, and relieve soft tissue tension to recover normal tissue function by cutting and detaching local lesions.[12,13] In clinical practice, AT is a common treatment for KOA in China, due to the reasons that AT is easy to operate, low cost, and highly effective. At present, traditional AT locates the site and depth of the puncture site based on the experience, body surface bony landmarks, and the tactile feedbacks estimated by the physician from the AT.[14] Therefore, such operations are carried out without direct vision, leading to the possible impact on the clinical efficacy due to the inaccuracy of the therapeutic target locations, and may even damage some blood vessels and nerves.

AT visualization is the unavoidable future. Some previous studies found that ultrasound-guided acupotomy (UGAT) improves the efficacy and cause fewer complicating syndromes, comparing to traditional AT.[15] However, these clinical researches are still at the primary stage, and no meta-analysis regarding this topic has been conducted previously, while the usage of UGAT for KOA treatment still has no convincing supportive study.

In this study, systematic reviews and meta-analyses of randomized controlled trials (RCTs) were conducted in order to compare the effectiveness and safety of UGAT with other therapies (traditional AT, acupuncture, and electroacupuncture [EA]) in the treatment of KOA.

2. Materials and methods

2.1. Research strategies and selection criteria

Independently researches were carried out by 2 researchers (JXW and YTL) in 6 academic databases: PubMed, the Cochrane Library, EMBASE, the China national knowledge infrastructure, the Wan Fang databases, and the Chinese biomedical literature database to identify relevant articles, from their inception to January 1, 2022. The following search terms were used: ("acupotomy," "needle scalpel," "needle knife," "acupotome"), ("ultrasound," "ultrasonography," "ultrasonic," "ultrasonics"), and ("Knee Osteoarthritides," "Osteoarthritides, Knee," "Knees, Osteoarthritis Of"). Detailed search criteria for PubMed were listed in Appendix S1, Supplemental Digital Content, http://links.lww.com/MD/I331. In addition, potentially relevant studies were checked individually to ensure that there were no missing papers. There was no language limitation.

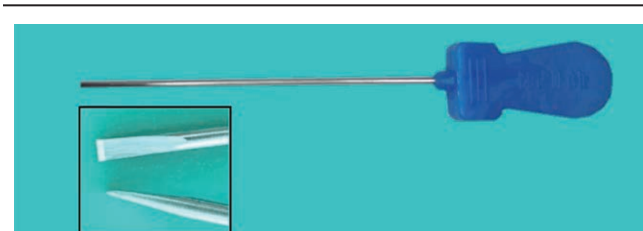

Figure 1. The diagram of the shape of acupotomy.

2.2. Studies selection

2.2.1. Inclusion criteria.

(1) Types of participants: participants were patients with clinically confirmed KOA regardless of their age, race, sex, education, and employment.
(2) Types of interventions: UGAT (material of needles, acupoints, and ultrasonic equipment were not constrained).
(3) Types of control groups: conventional therapy generally used for KOA such as traditional AT, acupuncture, EA, and ultrasound-guided drug injection therapy were included.
(4) Types of outcome measures: primary outcome measures were score changes on the visual analog scale (VAS) and Lysholm knee score (LKSS); secondary outcome measures were clinical effective rate (ER), and adverse events.
(5) Types of studies: RCTs.

2.2.2. Exclusion criteria.

(1) Quasi-RCTs and randomized crossover studies.
(2) Duplicate reports, animal studies, case reports, and letters.
(3) Data in abstract forms, or data that were not completed.
(4) Involvement of additional treatments, or control group with additional treatments.
(5) Small sample size (less than 15 participants).

2.3. Data extraction and management

Two reviewers (JXW and YTL) independently undertook the extracted relevant data of each report that met the inclusion criteria. Any disagreements/inconsistency were resolved by thorough discussions, until consensus was achieved. This standardized form included 3 major domains: general information (such as name of first author, publication time, and location of study), experimental design (such as participant numbers, sex, age, trial methods, detailed procedures of the treatment and control groups, type of ultrasound device, total period, and outcome), and conclusion.

2.4. Assessing of the bias

Two reviewers (JXW and YTL) independently assessed the bias risks in each literature studied using the Cochrane "Risk of bias" tool. It included 6 domains of bias: selection bias (method of randomization and allocation concealment), performance bias (blinding of personnel and participants), detection bias (blinding of the result assessor), attrition bias (incomplete result data), reporting bias (selective reporting), and other biases (baseline balance and fund). The risk of bias for every domain was categorized as entailing a low, unclear, and high.

2.5. Statistical analyses

All statistical analyses were conducted by Review Manager version 5.3 software (https://training.cochrane.org/online-learning/core-software/revman). For continuous outcomes (VAS and LKSS), mean differences (MD) and 95% confidence interval (CI) were subjected to quantitative analysis data of each group. Relative risk (RR) or odds ratio combined with 95% CI were evaluated for dichotomous data (ER and adverse events). For each study, P value lower than .05 was considered as statistically significant. Statistical heterogeneities among studies were evaluated using the chi-squared test and the Higgins I^2 measure. When test values indicated moderate heterogeneity ($P < .1$ and $I^2 > 50\%$) random rather than fixed-effects models were applied. To compare with different control groups, further analyses were conducted. To estimate the robustness of the findings, we conducted a sensitivity analysis. Moreover, visual observation of funnel plot was subjected to the evaluation of potential publication bias if sufficient studies were included (n ≥ 10).

2.6. Quality of evidence

We used the grading of recommendations assessment, development, and evaluation[16] methodology to evaluate the qualities of evidences for all meta-analyses, and categorized them into high, moderate, low, or very low.

3. Results

3.1. Literature selection

In accordance with the retrieval strategies, 115 potentially relevant studies were retrieved. Further, we excluded 27 duplicates studies by using EndNote X7 software (https://endnote.com/downloads) and excluded 40 studies due to inappropriate diagnosis and wrong intervention measures. After reading the full contents of all remaining articles, 40 studies were excluded for reasons such as no RCTs were included or insufficient data. Finally, 8 studies[17–24] were included in this systematic review. Figure 2 shows the flow diagram describing the process of studies selection.

3.2. Characteristics of included literature

The main features of the included studies were listed as in Table 1. Trials included in this study were all carried out in China. All results were published from 2013 to 2019, with a total of 543 participants. Among them, the sample size ranged from 48 to 123. The baseline data of the included studies demonstrated no significant difference. Based on the comparisons, 6 studies[17–22] compared UGAT with traditional AT, 1 study[23] compared UGAT with EA, and 1 study[24] compared UGAT with manual acupuncture (MA). Moreover, the average treatment time ranged from 2 to 5 weeks.

3.3. Methodological quality of included studies

As shown in Figures 3 and 4, the results of risk of bias assessment of all included studies were summarized. Among the 8 included studies, 2 studies[18,22] employed computer random number generator, 3 studies[21,23,24] used applied random number table, and the remaining 3 studies[17,19,20] only mentioned "random" without provide details of the randomization procedure. Two studies[21,22] used sealed opaque envelopes, and other studies did not describe allocation concealment. Given this type of trials were quite difficult to blind participants and personnel completely, we therefore rated them as high risk, with the exception of only 2 studies[18,22] clearly reported the blinding of outcome assessment. Regarding incomplete data, 3 studies reported dropout numbers and reasons. Additionally, the presentation of "reporting bias and other biases" were lacked in all included studies.

3.4. Results of meta-analysis

3.4.1. VAS. The 8 studies[17–24] (including 543 patients) included to evaluate the pooled estimation for assessing the VAS score revealed that UGAT could decrease the VAS score

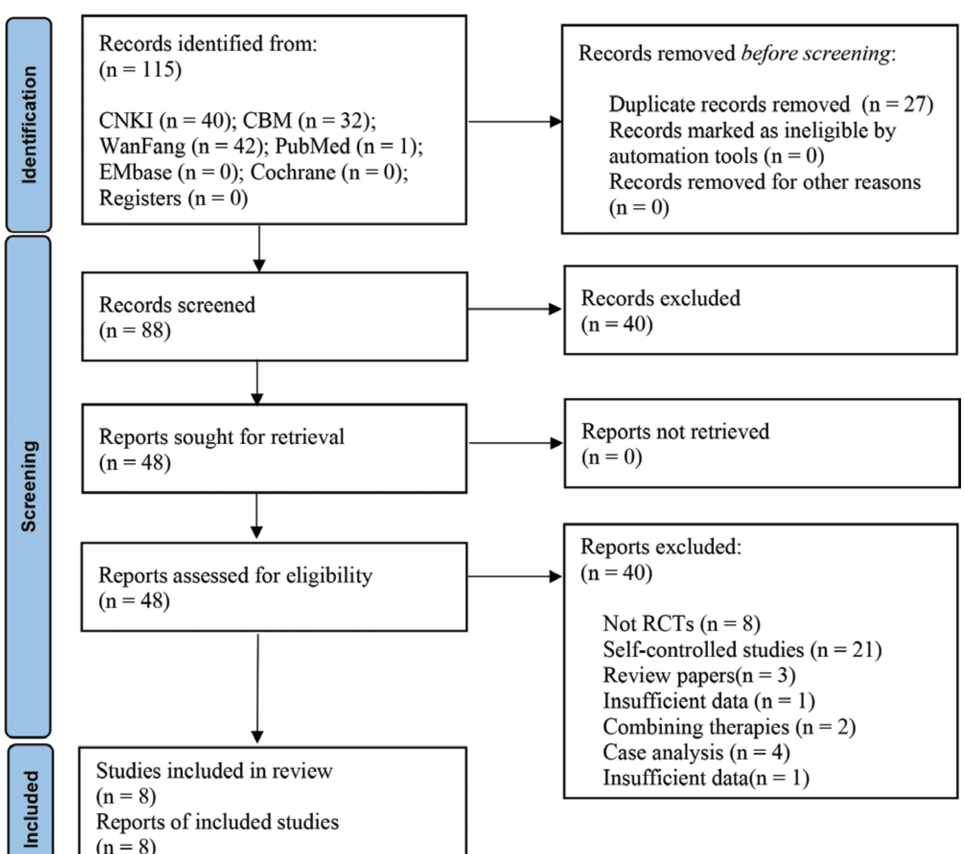

Figure 2. Flow diagram of the study.

Table 1

Features of the included studies.

Author (yr)	Study location	Sample size	Female/male	Age (yr)	Experimental group	Control group	Outcome measures	Adverse events	Ultrasound probe
Ma and Ding (2013)[17]	Beijing, China	48	E: 8/16 C: 10/14	E: 45–71 C: 50~73	UGAT 1 time per week (3 wk)	AT 1 time per week (3 wk)	VAS	Yes	7–12 MHz
Ruan and Zeng (2017)[18]	Guangdong, China	60	E: NR C: NR	E: 50–80 C: 50–80	UGAT 1 time per week (5 wk)	AT 1 time per week (5 wk)	VAS, ER	NR	7–12 MHz
Deng (2019)[19]	Guangdong, China	78	E: 28/11 C: 26/13	E: 56.3 ± 4.6 C: 56.1 ± 4.7	UGAT 1 time per wk (3 wk)	AT 1 time per week (3 wk)	VAS, ER, LKSS	NR	7–12 MHz
Li (2019)[20]	Hubei, China	55	E: 10/18 C: 11/16	E: 54.7 ± 5.4 C: 53.4 ± 4.3	UGAT 1 time per wk (3 wk)	AT 1 time per wk (3 wk)	VAS, ER	Yes	7–12 MHz
Zhong (2016)[21]	Guangdong, China	60	E: NR C: NR	E: 50–80 C: 50–80	UGAT 1 time per wk (3 wk)	AT 1 time per wk (3 wk)	VAS, ER	Yes	NR
Zhang (2019)[22]	Beijing, China	123	E: 12/47 C: 14/50	E: 57.3 ± 6.8 C: 58.7 ± 6.9	UGAT 1 time per wk (2 wk)	AT 1 time per wk (2 wk)	VAS, LKSS	Yes	15 MHz
Ding et al (2016)[23]	Beijing, China	60	E: NR C: NR	E: 42–69 C: 42–69	UGAT 1 time per wk (3 wk)	EA 5 times per wk (30 min, 3 wk)	VAS, ER	NR	NR
Li et al (2018)[24]	Hebei, China	60	E: 8/22 C: 11/19	E: 65.7 ± 4.5 C: 63.5 ± 4.1	UGAT 1 time per wk (2 wk)	MA 5 times per wk (30 min, 2 wk)	VAS, ER	NR	NR

AT = traditional acupotomy, C = control group, E = experimental group, EA = electroacupuncture, ER = effective rate, LKSS = Lysholm knee score, MA = manual acupuncture, NR = not reported, UGAT = ultrasound-guided acupotomy, VAS = visual analogue scale.

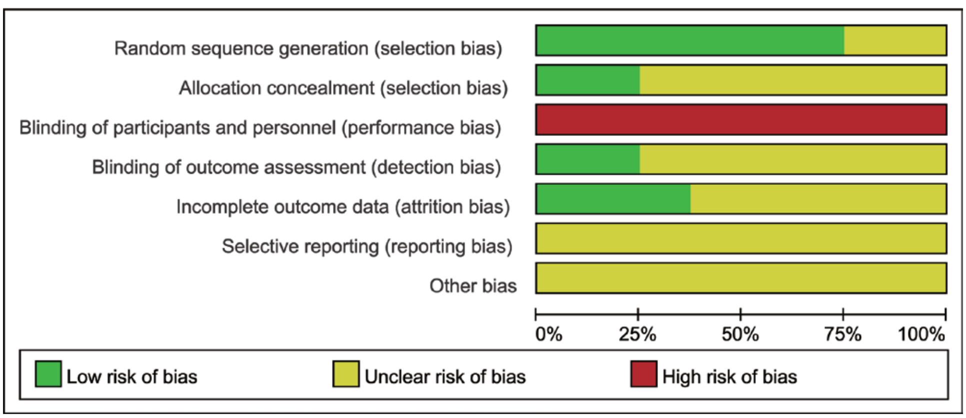

Figure 3. Risk of bias.

more significantly in comparing with the control group (MD = −0.81, 95% CI = [−1.15, −0.47], $P < .00001$). However, there was moderate statistical among these RCTs ($\chi^2 = 14.39$, $P = .04$, $I^2 = 51\%$), while a random-effects model was applied. We performed a sensitivity analysis and found that 1 study (Ma and Ding[17]) was removed, and the remaining studies were considered homogeneous and the results were stable (MD = −0.76, 95% CI = [−0.97, −0.55], $P < .00001$; $\chi^2 = 4.07$, $P = .80$, $I^2 = 0\%$). For the study of heterogeneity, subgroup analysis was subjected according to the different types of comparison groups: traditional AT, EA, and MA. Subgroup analysis demonstrated positive effects of UGAT on pain relief in comparing with AT (MD = −0.82, 95% CI = [−1.29, −0.36], $P = .0005$; $P = .02$, $I^2 = 64\%$; 6 study, 423 participants), EA (MD = −0.70, 95% CI = [−1.37, −0.03], $P = .0005$; 1 study, 60 participants), and AT (MD = −1.00, 95% CI = [−1.74, −0.26], $P = .0005$; 1 study, 60 participants) (Fig. 5).

3.4.2. LKSS. Two studies[19,20] reported that the LKSS was used to evaluate knee joint function. The meta-analysis indicated that UGAT could further improve knee function compared with AT (MD = 8.26, 95% CI = [1.56, 14.97], $P = .02$). The result was obvious heterogeneity ($\chi^2 = 4.06$, $P = .04$, $I^2 = 75\%$) and a random effects model was applied (Fig. 6).

3.4.3. Clinical ER. Six studies[18–21,23,24] reported the clinical ERs of these 2 groups of patients. Data extracted showed no significant heterogeneity ($\chi^2 = 5.58$, $P = .35$, $I^2 = 10\%$) in these RCTs, therefore a fixed-effect model was applied to evaluate the pooled RR and 95% CI. The data demonstrated that the clinical efficacy rate improved significantly in the UGAT group versus the control group (RR = 1.14, 95% CI = [1.06, 1.23], $P = .005$). According to the different types of comparison groups, subgroup analyses were conducted. Subgroup analysis also showed that UGAT was statistically significantly better than AT (RR = 1.13, 95% CI = [1.04, 1.23], $P = .004$) with no heterogeneity ($\chi^2 = 2.42$, $P = .49$, $I^2 = 0\%$) and MA (RR = 1.35, 95% CI = [1.02, 1.79], $P = .04$). However, no difference was detected between UGAT and EA based on 1 study (RR = 1.04, 95% CI = [0.89, 1.21], $P = .64$) (Fig. 7).

3.4.4. Adverse events. Four studies[17,20–22] reported adverse events occurred in the 2 groups during the treatments, including hematomas, local painful sensation, bleeding, swelling of the joint, and slight nerve damage. All adverse events were shown in Table 2. Analysis of data showed no heterogeneity ($\chi^2 = 1.70$, $P = .64$, $I^2 = 0\%$), and the fixed-effects model demonstrated that adverse event rates were significantly lower for UGAT (odds ratio = 0.27, 95% CI = [0.12, 0.63], $P = .002$) compared to AT (Fig. 8).

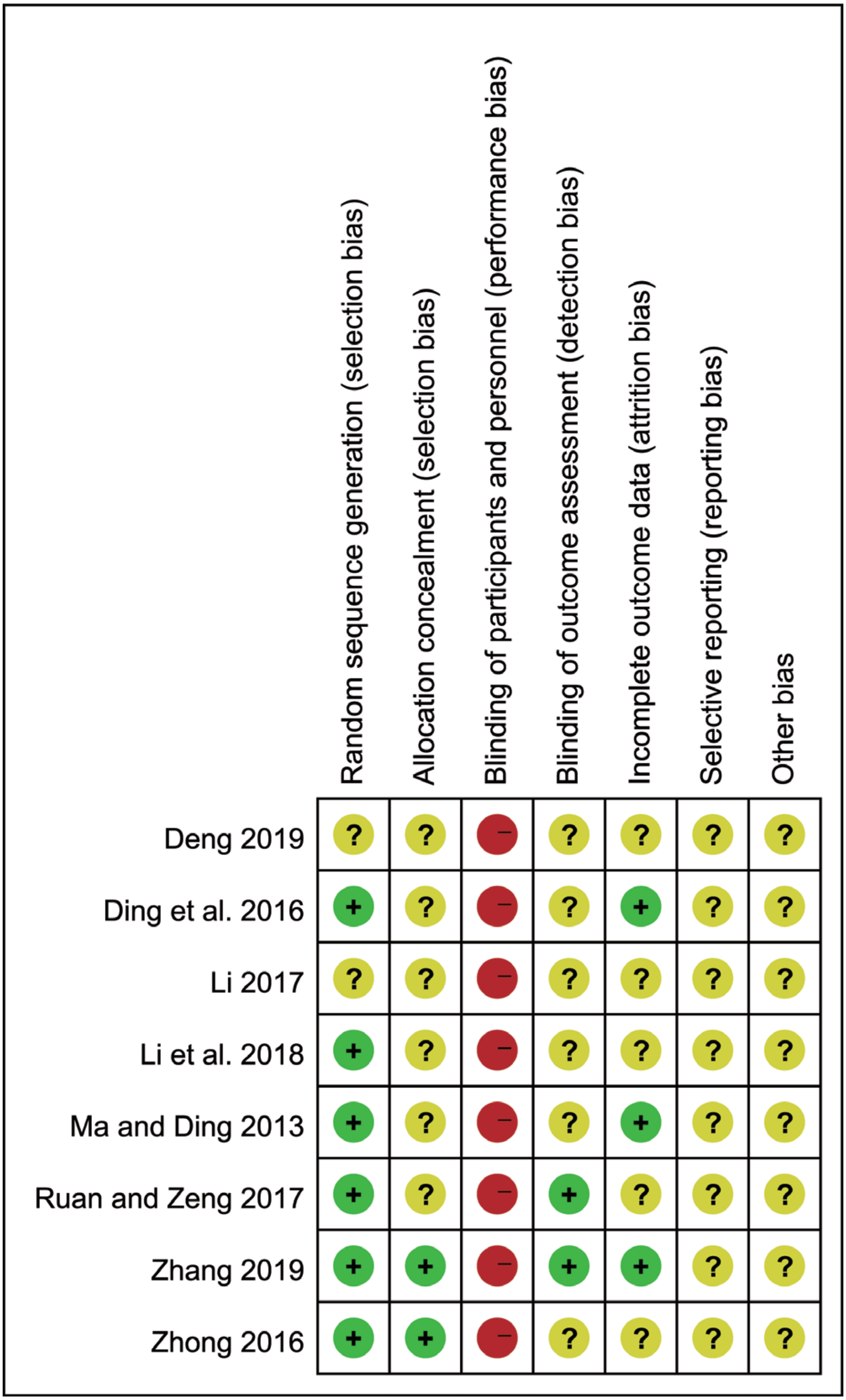

Figure 4. Risk of bias summary.

3.4.5. Level of evidence. Based on the results of the grading of recommendations assessment, development, and evaluation criteria, the qualities of evidences for most comparisons were rated within the region of very low to low (Table 3). Most of the studies did not report blinding of personnel and participants, allocation concealment, and the outcomes and reason of the adverse event was not sufficiently described, leading to the result that the qualities of evidences were initially downgraded. Also, the significant heterogeneity and small sample sizes led to imprecision also downgraded the evidence level.

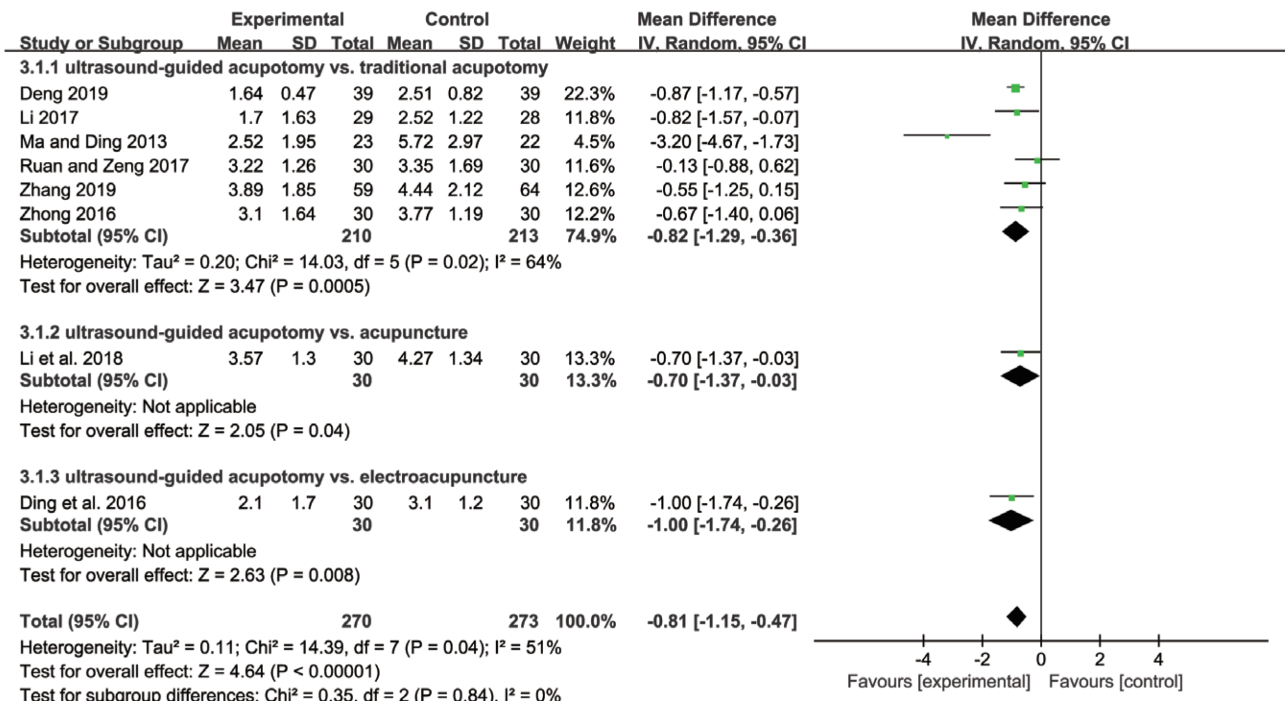

Figure 5. Forest plot of ultrasound-guided acupotomy group versus control group: visual analog scale (VAS).

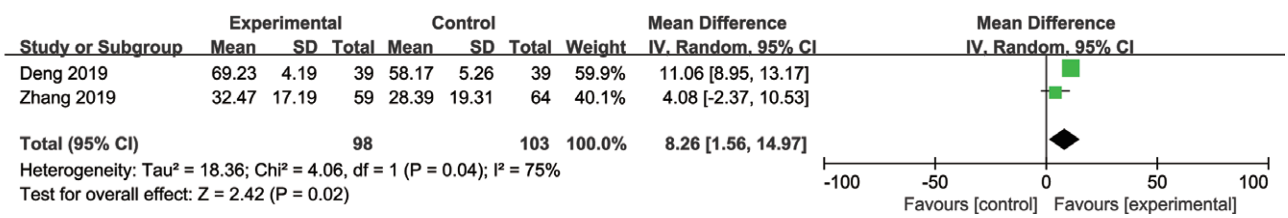

Figure 6. Forest plot of ultrasound-guided acupotomy group versus control group: Lysholm scores (LKSS). LKSS = Lysholm knee score.

4. Discussion

4.1. Principal findings

This study was the first meta-analysis aimed to evaluate the effectiveness and safety of the UGAT therapy for treatments of KOA. After a comprehensive research of the major academic databases, 8 studies with 543 participants were included in this meta-analysis. From the available data, the present meta-analysis demonstrated that UGAT were effective for KOA as follows: With respect to LKSS and VAS score, UGAT was superior in improved knee function and pain relief compared with the control group based on the very low-quality evidence. In the subgroup analysis, the results were not significantly changed in different types of comparison groups. Sensitivity analysis demonstrated that the data in this meta-analysis were relatively stable. The low-quality evidences showed that UGAT was more effective than AT and MA. However, no statistical significance was demonstrated between UGAT and EA based on 1 study. UGAT significantly reduced incidence of adverse events compared with AT. These seemingly positive results should be interpreted with caution due to the low methodology quality, a limited sample size, and the language limitation of the included trials.

4.2. Mechanism of AT on KOA

The underlying mechanisms of AT for KOA was not clear; however, it demonstrated a positive therapeutic effect on KOA. The theory of traditional Chinese medicine suggests that trauma to the sinews, and cumulative fatigue entangled in the fascia' muscle may form "strips" and "nodules,"[25] which would obstruct the channels and eventually lead to knee diseases. AT therapy was beneficial to release "strips," "nodules," and relieving spasms in the surrounding ligaments and tendons to recover joint functions.[26,27] In addition, recent studies indicated that the mechanism of AT therapy potentially associated with decreased inflammatory cytokine levels,[28] improved skeletal muscle fibrosis,[29] regulating biomechanical properties of ligament,[30] inhibition of chondrocyte apoptosis,[31] and repairing the damage of cartilage to some extent.[32]

4.3. Advantages of UGAT in KOA

Traditional AT treatment was a closed procedure that its efficacy and surgical safety depend on the operator's familiarity with local anatomy and technical level.[33] Hence, visualization of AT therapy was the best way to ensure the safety and effectiveness. With the development of ultrasound-guided techniques, they have been commonly applied as an effective tool for interventional diagnosis and treatments of musculoskeletal and articular diseases.[34] AT guided by ultrasound for KOA had several advantages as follows. First, it has the characteristics of convenient, noninvasive, non-radiation, and flexible; second, the real-time ultrasonic images were able to display the position of AT and nearby structures precisely, which had good accuracy and safety; third, ultrasound images were easily observed from layers of the tissue structures, therefore the location and type of lesions were accurately identified; finally, it was also conducive to learning and dissemination. Therefore, UGAT had broad application prospects in the future.

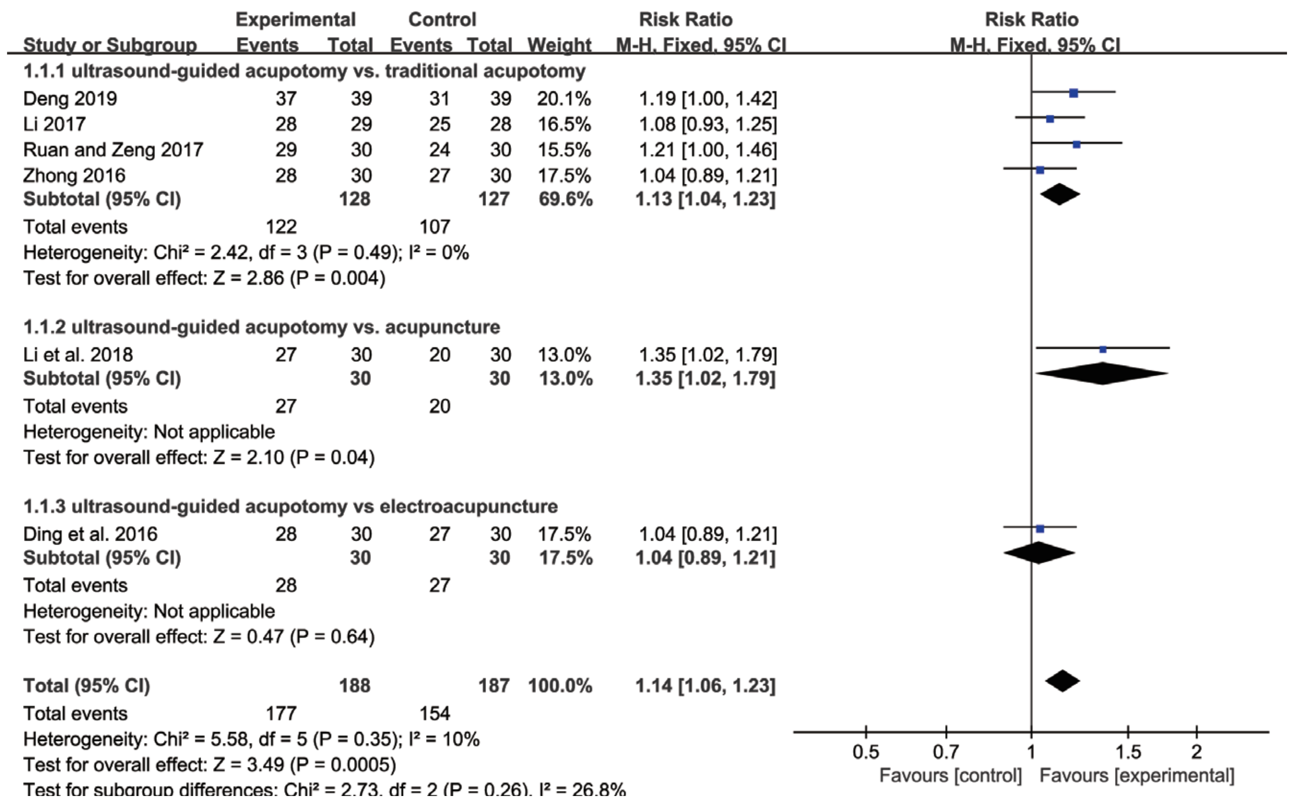

Figure 7. Forest plot of ultrasound-guided acupotomy group versus control group: efficacy rate (ER). ER = effective rate.

Table 2

The adverse events about all included RCTs.

Adverse events	Ultrasound-guided acupotomy N	Ultrasound-guided acupotomy Total	Traditional acupotomy N	Traditional acupotomy Total
Slight nerve damage[17]	1	23	3	22
Hematomas[17,20,22]	2	141	10	144
Local painful sensation[17,22]	2	82	3	86
Swelling of the joint[21,22]	0	84	5	92
Bleeding[21,22]	3	84	5	92

RCTs = randomized controlled trials.

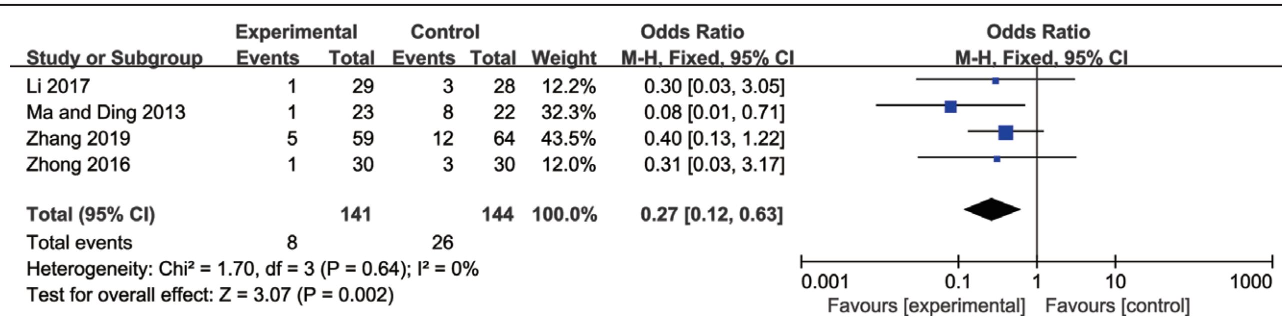

Figure 8. Forest plot of ultrasound-guided acupotomy group versus traditional acupotomy: adverse events.

4.4. Limitations of these studies

In this study, potential limitations of meta-analysis revealed possible impacts in the interpretation of our findings. First, sample sizes of most included studies were relatively small, causing the decrease of the overall precision of the estimations. Second, the methodological quality was low for most studies, especially lack of the details of blinding and allocation concealment. Meanwhile, no protocol or clinical trial registration were recorded for studies included in this, therefore the possibility of selective reporting were not clear. Third, there was significant heterogeneity across included studies. Although subgroup analysis was conducted, heterogeneity has not been resolved. The methodological bias, differences in treatment points selection, and duration of treatment may have contributed to the

Table 3

The quality of evidence.

Outcomes	No. of study (subjects)	DD	IN	HE	RI	PB	Quality of the evidence
VAS	8 (543)	−1[A]	0	−1[B]	0	−1[D]	+/−/−/−/; very low
LKSS	2 (201)	−1[A]	0	−1[B]	−1[C]	−1[D]	+/−/−/−/; very low
ER	6 (331)	−1[A]	0	0	0	−1[D]	+/+/−/−/; low

A: study design defects may affect the results; B: significant heterogeneity; C: very few participants may affect the results; D: publication bias may affect the results.
DD = design defects, ER = effective rate, HE = heterogeneity, IN = indirectness, LKSS = Lysholm knee score, PB = publication bias, RI = data sparse or incomplete, VAS = visual analog scale.

heterogeneity. Finally, ultrasound sonographic relevant indices, such as joint effusion and synovial thickness, were not assessed, and adverse events were underestimated.

5. Conclusion

In conclusion, despite the limitations of the methodology, our results of meta-analysis indicated the potential use of UGAT therapy as an effective and safe method in the clinical treatments of KOA, and could be applied in the management of KOA. To strengthen supportive evidence, more large-scale, long-term follow-up and high-quality RCTs were recommend in future.

Author contributions

Conceptualization: Sixiong Lin, Renpan Zhang.
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Software: Sixiong Lin.
Writing – original draft: Sixiong Lin, Chuanshi Lai, Renpan Zhang.
Writing – review & editing: Sixiong Lin, Renpan Zhang.

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