

Research Article

The Effectiveness and Safety of Acupotomy in Visualization Technique on Knee osteoarthritis: A Systematic Review and Meta-analysis

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Abstract

Objective: This study is to assess the efficacy and safety of acupotomy visualization in Knee Osteoarthritis (KOA).

Methods: We searched for relevant studies in PubMed, the Cochrane Library, Embase, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), the Wanfang Data, and the Chinese Scientific Journal Database (VIP) from their inception to October 2023. Randomized controlled trials on the effectiveness of acupotomy visualization for the treatment of KOA were included. Two reviewers screened each literature and extracted data independently according to Cochrane Reviews' Handbook (5.1). Meta-analysis was conducted using StataSE-64. The continuous data were presented as the mean difference (MD) with 95% confidence intervals (CI), while dichotomous data were described in terms of relative risk (RR) or odds ratio (OR) with 95% CI.

Results: We identified 11 studies involving 834 patients. The result indicated significant improvement of KOA following acupotomy [clinical effectiveness: OR =5.21, 95% CI: 3.04~8.92, P <0.001; pain score: MD =-0.67, 95% CI: -0.86~-0.48, P<0.001; ROM: SMD = 0.99, 95% CI: 0.711.26, P < 0.001]. In addition, the acupotomy visu-

alization groups had fewer adverse events than the control groups [RR=0.19, 95%CI: 0.06~0.57, P=0.003<0.05].

Conclusion: Acupotomy visualization is a safe and effective treatment for KOA. However, due to the methodological deficiencies of the included studies, well-designed randomized controlled trials are required to further confirm the findings.

Keywords: Acupotomy; Clinical effectiveness; Knee osteoarthritis; Meta-analysis; Visualization

Introduction

KOA is a chronic degenerative disease of the knee joint causing pain, restricted motion and disability of the knee joint in patients with KOA. It has become a major health problem worldwide [1-4]. Recently, World Health Organization report on the global burden of disease indicates that KOA is likely to become the fourth most important cause of disability in women and the eighth most important cause in men [5-8]. For example, the incidence of this disease in Sweden is estimated at approximately 15.4% among adults aged from 56 to 84 years [9,10]. With the increasing ages of the general population, the prevalence of KOA is gradually increasing, negatively affecting the quality of human life and bringing economic burden [11-14]. The therapies for KOA mainly include non-steroidal anti-inflammatory drugs (NSAIDs) and surgery [15]. However, NSAIDs often induce gastrointestinal reactions, like gastric perforation, gastric ulcers and bleeding, leading to a poor quality of life in patients with KOA. Surgeries are expensive and the risk of surgery is unpredictable [16-18]. Due to these disadvantages, increasing numbers of patients with KOA are turning to alternative therapies. In China, traditional acupotomy has been widely used to relieve pain in patients with KOA, due to traditional acupotomy is easy to operate, low cost, and effective.

Traditional acupotomy is a minimally invasive therapy of traditional Chinese medicine, which consists of traditional acupuncture and modern surgical principles. It can dredge meridians and release tissue adhesion because the specific bit tool of traditional acupotomy could needle, cut, strip, and shove. The effectiveness of traditional acupotomy in treating KOA has been shown in lots of studies. However, the safety of traditional acupotomy is often questioned, because it is a closed procedure that relies on sensations in doctors' hands [19,20]. Some scholars think that nerves, blood vessels and organs may be damaged during traditional acupotomy operation.

Acupotomy visualization is an excellent way to improve the safety of traditional acupotomy [21]. This therapy helps doctors find treatment points accurately and steer the incision trajectory, decreasing the incidence of adverse events. Studies have reported that acupotomy visualization is effective and safe to treat patients with cervical spondylosis [22], trigger

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fingers [23] and tenosynovitis [24]. In this study, we chose the large sample size of randomized controlled trials (RCTs) to make systematic reviews and meta-analyses for the effectiveness and safety of acupotomy visualization in the treatment of KOA.

Methods

Protocol and Registration

The protocol for the meta-analysis is registered with PROSPERO (CRD 42021271097). This meta-analysis was reported according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement and recommendations.

Research strategy and screening process

Independently researches were carried out by 2 researchers (SXX and ZLP) in 7 academic databases: PubMed, the Cochrane Library, Embase, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), the Wanfang Data, and the Chinese Scientific Journal Database (VIP) to identify relevant articles, from their inception to October 2023. The PubMed search strategy is presented as an example, and searches of other databases were conducted following the same strategy. Detailed search criteria for PubMed were listed in table 1.

Number	Search terms
#1	"randomized controlled trial" pt, OR "controlled clinical trial" [pt] OR randomized" [ti, ab] OR "placebo" [ti, ab] OR "trial" [ti, ab] OR "groups" [ti, ab]
#2	"clinical trials as topic" [mesh: noexp]
#3	#1 OR #2
#4	"acupotomy" [ti, ab] OR "needle scalpel" [ti, ab] OR "needle knife" [ti, ab] OR "ORacupotomlogy" [ti, ab] OR "miniscalpel acupuncture" [ti, ab] OR "miniscalpelneedle" [ti, ab] OR "stiletto needle" [ti, ab] OR "Xiaozhendao" [ti, ab]
#5	"Osteoarthritis, Knee" [Mesh] OR "Knee Osteoarthritis" [ti, ab] OR "KneeOsteoarthritis" [ti, ab] OR "Osteoarthritis, Knee" [ti, ab] OR "Osteoarthritis Of Knee" [ti, ab] OR "Knee, Osteoarthritis Of", [ti, ab] OR "Knees, Osteoarthritis Of" [ti, ab]
#6	"Ultrasonography" [Mesh] OR "Diagnostic Ultrasound" [ti, ab] OR "Diagnostic Ultrasounds" [ti, ab] OR "Ultrasound, Diagnostic" [ti, ab] OR "Ultrasounds, Diagnostic" [ti, ab]
#7	#3 AND #4 AND #5 AND #6

Table 1: Detailed search criteria for PubMed.

Two reviewers (SXX and ZLP) 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 2 major domains: general information (such as name of first author and publication time of study), experimental design (such as participant numbers, sex, age, trial methods, detailed procedures of the treatment and control groups, total period, and outcome), and conclusion.

Inclusion criteria

(1) Patients: Enrolled patients had a clear pathological diagnosis of KOA. Diagnostic criteria refer to: ①2007 or 2019 edition of the Chinese Medical Association Orthopaedic Branch Bone and Joint

Diagnosis and Treatment Guidelines [25,26] ②1995 edition of the American Rheumatism Association Diagnostic Criteria [27]. If the specific diagnostic criteria are not recorded in the study, the diagnosis of KOA must be based on important identifiable features [28]. (2) Intervention: The treatments only included acupotomy visualization. (3) Comparison: The control groups included common therapies such as intra-articular injections, traditional acupotomy, or acupuncture. (4) Outcome: The clinical effectiveness was extracted as the primary outcome using the following criteria: ①HSS Knee Score: cure = improvement rate of KOA score > 75%; significantly effective= improvement rate of score 50% to 75%; slightly effective= improvement rate of score 25% to 49%; ineffective = improvement rate of score < 25%. ②WOMAC Knee Score: cure = ≥90% reduction in points; significantly effective = ≥60% and <90% reduction in points; slightly effective = ≥30% and <60% reduction in points; ineffective = <30% reduction in points. ③The 1995 edition of the "Diagnostic and Therapeutic Criteria for Chinese Medical Evidence"; secondary outcomes included the Visual Analogue Scale (VAS), widely used to assess treatment outcomes in KOA; ROM; the incidence of adverse events. (5) Study design: Randomized Controlled Trials (RCT).

Exclusion criteria

The following studies were excluded:(1) studies using acupotomy visualization in both groups; (2) duplicate studies; (3) literature reviews, abstracts, personal academic opinions, conference reports, and case reports; (4) study data results which were incomplete, or from which data could not be extracted.

Data extraction and quality assessment

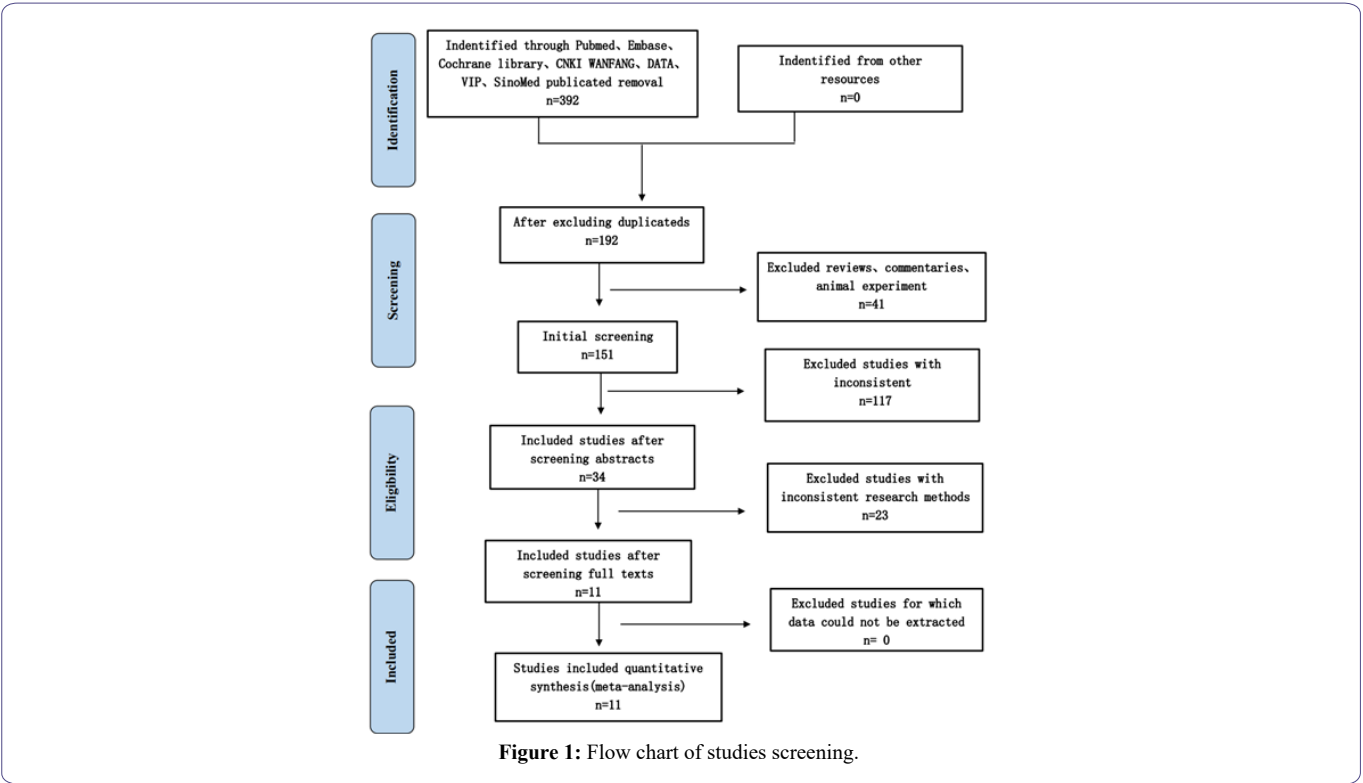
Two researchers independently extracted and tabulated data from the included studies. The following data were extracted: first author, publication year, patient characteristics, interventions, treatment duration, study outcomes, adverse events, and other details (Table 2).

The risk of bias was assessed by two reviewers independently (SXX and ZLP). Disagreements were settled by discussion and analysis between reviewers. The quality of included studies was assessed using the Cochrane Collaborations tool for assessing the risk of bias, which is recommended for systematic review of interventions in the Cochrane Handbook version 5.1.0 [29] According to this tool, two researchers assessed the risk of bias of the included studies independently, based on seven items:①randomization sequence generation. ②allocation concealment. ③blinding of participants or personnel. ④blinding of outcome assessment. ⑤incompleteness bias. ⑥reporting bias. ⑦other sources of bias. The quality of evidence was graded on four levels: high, moderate, low, or very low.

Statistical Analyses

All statistical analyses were conducted by Review Manager version 5.3 and software StataSE-64. Chi-square test and I² value were used to assess heterogeneity in the meta-analysis. In the presence of heterogeneity, its sources were further investigated. After eliminating the effect of heterogeneity, the fixed-effect model was adopted. Possible reasons for heterogeneity among articles were investigated by sensitivity, subgroup analysis or by descriptive analysis alone. When the heterogeneity was low, the fixed-effects model was used.

The results were expressed as the mean difference (MD) with 95% CI, while dichotomous data were described in terms of dd risk (OR) or relative risk (RR) with 95% CI. When the same intervention effect



Study	Popula- tion (T/C)	Female/Man	Age(T/C)	Course of disease (T/C)	Treat- ment	Control	Treat- ment frequency	Duration	Random- ization sequence genera- tion	Blinding	Outcome	Comple- teness
Ruan Yijun 2017[31]	30/30/30	----	----	----	acupo- tomy visualiza- tion	C1 tra- ditional acupoto- my C2in- tra-ar- ticular injection	1/1week	2-3weeks	computer random sampling	double blind	①⑤⑥⑦	yes
Deng Zhongyang 2019[32]	39/39	T (28/11) C (26/13)	T(56.32±4.68); C(56.17±4.73)	T(15.47±3.21) months C(15.52±3.45) months	acupo- tomy visualiza- tion	tradi- tional acupoto- my	1/2week	3weeks	random number table	no blind	①②⑤	yes
Li Mengting 2017[33]	30/30	T (10/18) C (11/16)	T(54.71±5.41) C(53.44±4.33)	T(15.89±4.72) months C(15.60±4.27)months	acupo- tomy visualiza- tion	tradi- tional acupoto- my	1/3week	3weeks	by visit time	no blind	①②③⑤	yes
Li Luning 2019[34]	36/32	T (11/25) C (9/23)	T(57.42±7.91) C(58.69±6.75)	T(5.31±2.83) years C(5.38±2.72) years	acupo- tomy visualiza- tion	TuiNa	1/5-6days	2weeks	random number table	no blind	①④⑤	yes
Zhong Tingyuan 2016[35]	30/30/30	T (11/19) C1(13/17) C2(10/20)	T mean 49.52 C1 ean50.65 C2 mean39.93	----	acupo- tomy visualiza- tion	C1 tra- ditional acupoto- my C2in- tra-ar- ticular injection	1/1week	3weeks	random number table	triple blind	①④⑤⑥	yes

Li Luning 2018[36]	30/30	T (8/22) C (11/19)	T(57.03±7.17) C(57.27±6.20)	T(4.33±2.26) years C(4.50±2.26) years	acupotomy visualization	acupuncture	1/5-6 days	2weeks	random number table	no blind	①⑤	yes
Lin Qiaoxuan 2021[37]	46/46	T (30/16) C (31/15)	T(61.63±5.90) C(62.09±5.17)	T 4.00(12.50- 18.00) months C(14.91±5.91) months	acupotomy visualization	traditional acupotomy	1/1week	4weeks	computer random sampling	no blind	④⑤⑨	yes
Ma Yanhong 2013[38]	24/24	T (8/16) C (10/14)	T(45-71) C(50-73)	----	acupotomy visualization	traditional acupotomy	1/1week	3weeks	random number table	no blind	①⑧	no
Hu Guoqiang 2022[39]	50/50	T (29/21) C (30/20)	T(60.03±6.96) C(59.67±6.89)	T(5.83±2.64) years C(5.68±2.51) years	acupotomy visualization	traditional acupotomy	1/5days	10days	random number table	no blind	①④⑤	yes
Jiang Zhihao 2023[40]	36/36	T (16/20) C (14/22)	T(54.22±4.96) C(53.49±5.63)	T(2.25±0.62) years,C(2.12±0.55) years	acupotomy visualization	traditional acupotomy	1/1week	3weeks	random number table	no blind	③⑨	yes
Liu Jing 2022[41]	38/38	T (15/23) C (14/24)	T(53.00-58.25) C(55.00-59.00)	T(3.00-5.00)years C(2.75-5.00)years	acupotomy visualization	traditional acupotomy	1/1week	4weeks	random number table	no blind	①④	yes

Table 2: Basic features of the included studies.

Note: T: treatment group; C: control group; C1: control group 1; C2: control group 2

①VAS: Visual Analogue of Score;②Lysholm: Lysholm scale of knee joint; ③HSS: Knee HSS Scale;④WOMAC: The Western Ontario and McMaster Universities Osteoarthritis Index;⑤Clinical effective rate;⑥Rom of knee ;⑦The amount of hydrops in suprapatellar bursa;⑧Incidence of complication;⑨Articular cartilage thickness

is measured by the same method or unit, weighted mean difference (WMD) is the appropriate choice. When the same intervention effect is measured by different methods or units, standardized mean difference (SMD) is the appropriate choice as the combined statistic [30]. Due to the different criteria of the measurement among the studies, SMD and 95% CI were used to express the intervention effect.

Results

A total of 392 records were retrieved, and after eliminating duplicates, the titles and abstracts of 192 records were screened. After a final screening, we included 11 studies with 834 patients. The screening process is detailed in figure 1.

Basic characteristics of included studies

Study Quality Assessment

The results showed high risk of bias in the study by Li Mengting 2017 [31], due to a semi-randomized method based on the order of patient consultation time. The randomization methods of Jiang Zhihao 2023 [32], HU Guoqiang 2022 [33], Liu Jing 2022 [34], Zhong Tingyuan 2016 [35], Li Luning2019 [36], Deng Zhongyang 2019 [37] and Li Luning 2018 [38] involved a random number table method, indicating low risk of bias. Similarly, studies by Ruan Yijun 2017 [39] and Lin Qiaoxuan 2021 [40] used computerized random sampling and were at low risk of bias. Ma Yanhong 2013 [41] assigned groups proportionally and was also at low risk of bias. Zhong Tingyuan 2016 [35] described allocation concealment in detail and was evaluated as at low risk of bias. None of the remaining studies reported allocation concealment and were found to be at unclear risk of bias. However, the invasive nature of traditional acupotomy makes it difficult to achieve subject and operator blinding. Therefore, lack of blinding was

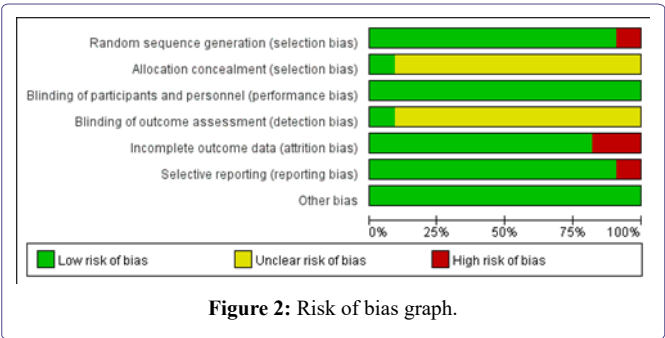
not considered to be a cause of bias. A study by Zhong Tingyuan 2016 [35] was triple-blinded and evaluated as at low risk of bias. Ruan Yijun 2017 [39] was double-blinded (subject and operator) and evaluated as at low risk of bias, but the blinding of outcome assessment was evaluated as at unclear risk of bias. The remaining studies did not specify whether the outcome evaluators were blinded, and all were evaluated as at unclear risk of bias. Studies by Li Mengting 2017 [31] and Ma Yanhong 2013 [41] have patient drop out and stated the reasons, so both were evaluated as at high risk of bias, while the remaining studies were evaluated as at low risk of bias; Ma Yanhong 2013 [41] selectively reported the results and was evaluated as at high risk of bias, while the remaining studies were evaluated as at low risk of bias because the results section was consistent with the content of the methods section. All studies were free of conflicts of interest, with similar group characteristics at baseline, and were evaluated as at low risk of bias. Among the included studies, Zhong Tingyuan 2016 [35] was a high-quality study with all aspects at low risk of bias (Figures 2 & 3).

Meta-Analysis

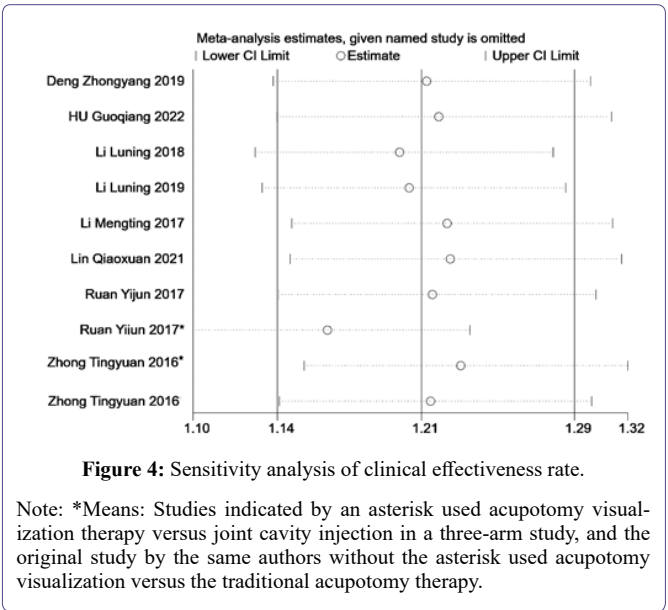
Clinical effectiveness of the acupotomy visualization technique

Eight of the articles included in this study addressed the clinical effectiveness. The meta-analysis of eight studies calculates the clinical effective effect size and to perform an observation. And the result of eight RCT data showed heterogeneity. (I2=44.0%<50%; P=0.066<0.10).

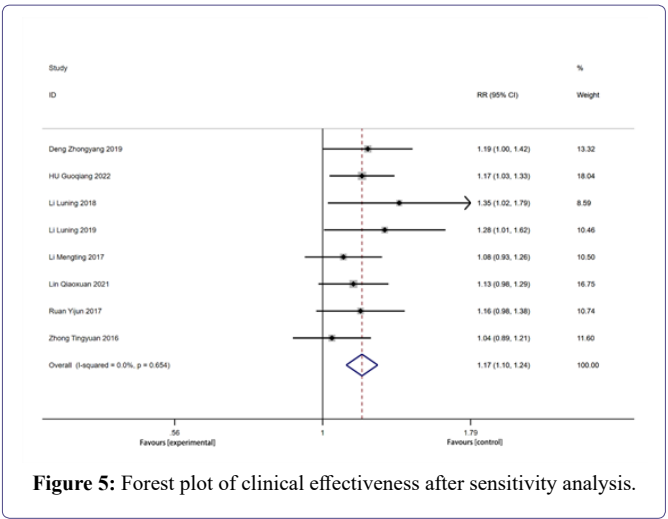
Sensitivity analysis was performed on 10 studies (two studies consists of three groups, so their control groups were split into two study groups). And study by Ruan Yijun 2017* and study by Zhong Tingyuan 2016* were found to have a large effect on heterogeneity (Figure 4).



The results of the repeat heterogeneity test after removing two studies showed no heterogeneity among the other eight studies ($I^2=0.0\%<50\%$; $P=0.654>0.1$). The fixed-effects model was applied for statistical analysis. Results indicated statistical significance of the clinical effectiveness of acupotomy visualization [RR =1.17, 95%



CI:1.10~1.24, $P<0.001$] (Figure 5). The results showed that the clinical effectiveness of the acupotomy visualization for KOA was significantly higher than that of other treatment methods.

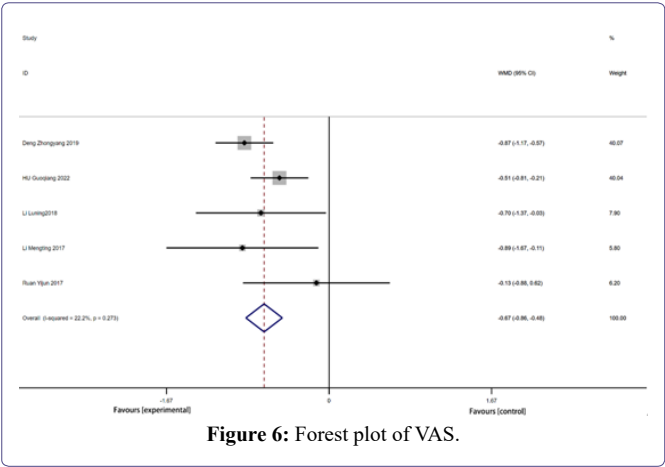


Acupotomy visualization technique to improve knee pain

The VAS score was used in five of the included studies, with no heterogeneity among them ($I^2=22.2\%<50\%$; $P=0.273>0.1$) (Figure 6). Using fixed-effects model analysis, the pooled effect size was statistically significant (MD=-0.67, 95% CI: -0.86~-0.48, $P<0.001$). The results show significantly lower VAS scores in the acupotomy visualization group than in the control groups. This indicates that acupotomy visualization is more effective for knee pain improvement than traditional acupotomy and acupuncture.

Effect of acupotomy visualization on ROM

Four of the articles included in this study addressed the ROM and there was heterogeneity among them ($I^2=89.3\%>50\%$; $P<0.001$). Analysis was performed using a random-effects model, and the weighted mean showed statistically significant effect of acupotomy on ROM (SMD=0.99, 95% CI: 0.71~1.26, $P<0.001$).



To search for the cause of heterogeneity, groups within the four studies were categorized into an acupotomy subgroup (NO.1) and a joint cavity injection of sodium hyaluronate subgroup (NO.2) according to the different interventions in the control groups. No heterogeneity was found among data within the two subgroups. Using the fixed-effects model, the effect size was statistically significantly different between the acupotomy group and the injection group. (The acupotomy group [SMD = 0.37, 95% CI: 0.01~0.74, P = 0.042], the injection group [SMD = 1.86, 95% CI: 1.43~2.29, P < 0.001], and overall [SMD=0.99, 95%CI:0.71~1.26, P < 0.001]). The results show that the ROM of the acupotomy visualization group is significantly greater than that of the control groups (Figure 7).

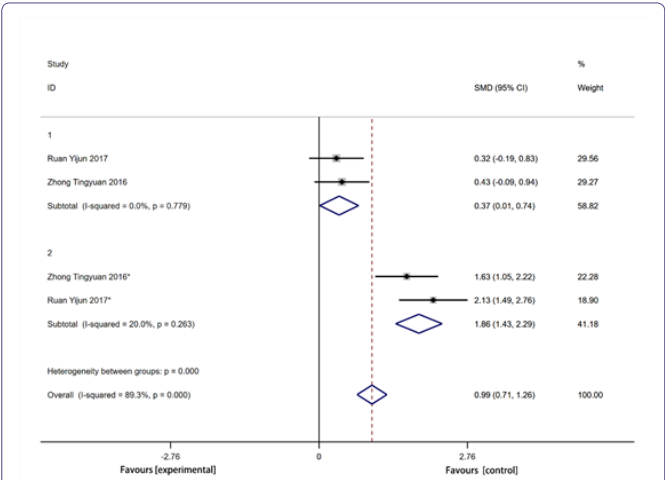


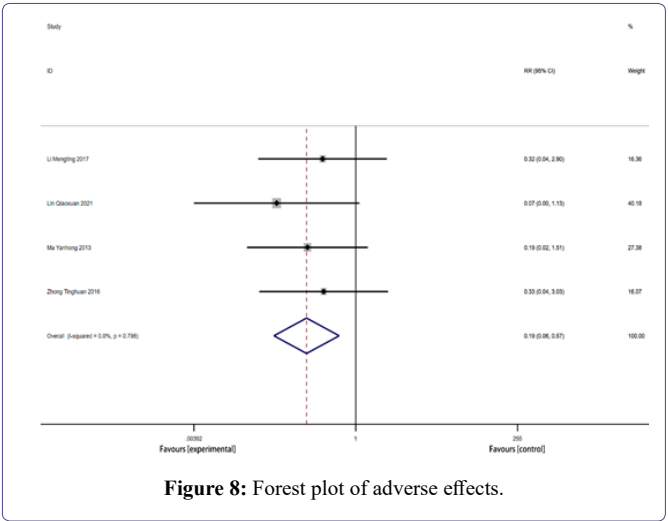
Figure 7: Forest plot of traditional acupotomy and joint cavity injection of sodium hyaluronate subgroup.

Adverse effect rates of acupotomy visualization therapy

Adverse effects were reported in four of the included studies with no heterogeneity among them (I² = 0%; P = 0.98). The pooled effect size [RR = 0.19, 95% CI: 0.05~0.49, P = 0.001] was statistically significant when a fixed-effects model analysis was applied. The results show a significantly lower rate of adverse effects in acupotomy visualization groups than in control groups (Figure 8).

Analysis of publication bias

Since fewer than 10 of the publications in this study included all outcome indices, no publication bias analysis was performed.



Discussion

Based on the Chinese traditional medical theory of Meridians and Tendons, traditional acupotomy regulates tendon to release tissue adhesions. Base on the modern medical theory of biomechanical balance, traditional acupotomy release ligaments, muscle tendons and bone retinaculums to improve the mechanical balance of the knee joint. Combined traditional acupotomy with ultrasound technology, acupotomy visualization is an innovation of traditional acupotomy. Compared with traditional acupotomy, real-time monitoring is the remarkable advantage of acupotomy visualization. Doctors can clearly distinguish the hierarchical structure of anatomy, accurately determine treatment points and observe the path of acupotomy operation. In addition, when doctors treat patients with KOA by acupotomy visualization, ultrasonic technique is also used to detect the pathological changes of KOA, like the destruction of bone, the abnormal echo of the meniscus [34] and so on. The eight articles included in this study explored the clinical effectiveness of acupotomy visualization in the treatment of KOA, and all of them concluded that this technology is worth promoting in the clinic for treatment of KOA.

When doctors choose the treatment points of traditional acupotomy, they guide by the experience and needling sensation without the involvement of any modern medical aid tools. Therefore, some scholars query the safety of traditional acupotomy, and they think the nerves and blood vessels around the knee may be injured. However, because acupotomy visualization is full visual and real-time monitoring, doctors can avoid injuring vital nerves, blood vessels and normal cartilages to protect the balance of stress points between knee with its surrounding tissues. The study of Qiu and Zeng [42,43] agree with above viewpoint, and they think that acupotomy visualization is safer and more effective than traditional acupotomy.

This study evaluates the effectiveness and safety of acupotomy visualization in the treatment of KOA. There are eleven articles used for meta-analysis, primarily from seven databases. There were four indexes, including clinical effectiveness, VAS scores, ROM and adverse effect rate. The results showed that the above four indexes in the acupotomy visualization group were better than those in the control group.

Suggestions for Future Research

Acupotomy visualization is generally recognized as a safe and effective treatment for KOA [44] and our study agrees with this perspective. However, this meta-analysis has some limitations, as follows: (1) The number of included studies was deficiency, (2) Due to ethical issues, blinding is challenging in the evaluation of acupotomy, resulting in few high-quality studies.

There are three suggestions, as follow: (1) it is recommended to add the scales of measuring pain levels in order to increase the rigor-ousness of experiments. (2) It is recommended to adverse events of acupotomy visualization with other therapies should be reported in detail to prevent bias (3) It is recommended to systematically standardize the measurement methods of outcome indicators to provide reliable evidences for clinical trials. We expect that the current study will provide more evidence for a deep understanding of acupotomy visualization in the treatment of KOA.

Conclusion

Acupotomy visualization can improve clinical effectiveness, relieve knee pain and increase ROM. As a new therapeutic technique, it is still being explored, and there are many aspects that need to be further improved.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Appendix 1

#1 “randomized controlled trial” [pt] OR “controlled clinical trial” [pt] OR “randomized” [ti, ab] OR “placebo” [ti, ab] OR “trial” [ti, ab] OR “groups” [ti, ab];

#2 clinical trials as topic [mesh: noexp];

#3 #1 OR #2;

#4 “acupotomy” [ti, ab] OR “needle scalpel” [ti, ab] OR “needle knife” [ti, ab] OR “acupotomlogy” [ti, ab] OR “miniscalpel acupunc-ture” [ti, ab] OR “miniscalpel needle” [ti, ab] OR “stileto needle” [ti, ab] OR “Xiaozhendao” [ti, ab];

#5 “Osteoarthritis, Knee” [Mesh] OR “Knee Osteoarthritis” [ti, ab] OR “Knee Osteoarthritis” [ti, ab] OR “Osteoarthritis, Knee” [ti, ab] OR “Osteoarthritis Of Knee” [ti, ab] OR “Knee, Osteoarthritis Of” [ti, ab] OR “Knees, Osteoarthritis Of” [ti, ab];

#6 “Ultrasonography” [Mesh] OR “Diagnostic Ultrasound” [ti, ab] OR “Diagnostic Ultrasounds” [ti, ab] OR “Ultrasound, Diagnostic” [ti, ab] OR “Ultrasounds, Diagnostic” [ti, ab];

#7 #3 AND #4 AND #5 AND #6;

The same search items will be used to search all electronic databases.

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