Systematic Review and Meta-Analysis

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Acupotomy for the treatment of lumbar spinal stenosis

A systematic review and meta-analysis

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Abstract

Background: Lumbar spinal stenosis (LSS) is caused by neural compression due to narrowing of the lumbar spinal canal or neural foramen. Surgical intervention is a standard treatment for LSS; however, the steep increase in the surgical rate, post-operative complications, and comparatively low long-term satisfaction are considered to be limitations of this surgical approach. Conversely, acupotomy is a minimally invasive technique that combines the effects of conventional acupuncture with micro-incision, which may offer an alternative to surgery for the treatment of LSS. This review was conducted to investigate and critically review the current evidence on the efficacy and safety of acupotomy for LSS.

Methods: Eleven databases were searched from their respective inception dates to December 28, 2018. Randomized controlled trials (RCTs) comparing acupotomy and wait-list, sham treatment, or active controls were included. The quality of the included studies was assessed using risk-of-bias tool.

Results: Seven RCTs were included in this review and meta-analysis. The methodological quality of the included studies was generally poor. The acupotomy treatment group was associated with significantly lower visual analogue scale scores (range 0~10) (5 RCTs; mean difference [MD] −1.55, 95% confidence interval [CIs] −2.60 to −0.50; I^2 = 94%) and higher Japanese Orthopedic Association Score (3 RCTs; MD 4.70, 95% CI 3.73 to 5.68; I^2 = 0%) compared to the active control group. In subgroup analysis based on the type of active controls, acupotomy retained significant benefits over lumbar traction and acupuncture, as well as over lumbar traction, spinal decompression, and acupuncture. Safety data were reported in only 1 study, and no adverse events occurred in either the acupotomy or the acupuncture control group.

Conclusion: According to current evidence, acupotomy might be beneficial for treating LSS. Acupotomy showed consistent superiority over lumbar traction, but the results were mixed in comparisons with other interventions, such as spinal decompression and acupuncture. However, the findings should be interpreted cautiously, given the poor methodological quality of the included studies, and potential small-study effects. Further larger, high-quality, rigorous RCTs should be conducted on this topic and rigorous reporting of acupotomy procedures and safety data should be encouraged.

Abbreviations: AMED = allied and complementary medicine database, CENTRAL = Cochrane central register of controlled trials, CIM = complementary and integrative medicine, CINAHL = cumulative index to nursing and allied health literature, CIs = confidence intervals, CNKI = China National Knowledge Infrastructure, JOA = Japanese Orthopedic Association, KCI = Korea Citation Index, LBP = low back pain, LSS = lumbar spinal stenosis, MD = mean difference, OASIS = Oriental Medicine Advanced Searching Integrated System, PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-analyses, PROSPERO = International Prospective Register of Systematic Reviews, RCTs = randomized controlled trials, RFT = percutaneous radiofrequency thermocoagulation, RISS = Research Information Service System, RR = risk ratio, STRICTA = Standards for Reporting Interventions in Clinical Trials of Acupuncture, TER = total effective rate, VAS = visual analogue scale.

Keywords: acupotomy, spinal stenosis, systematic review

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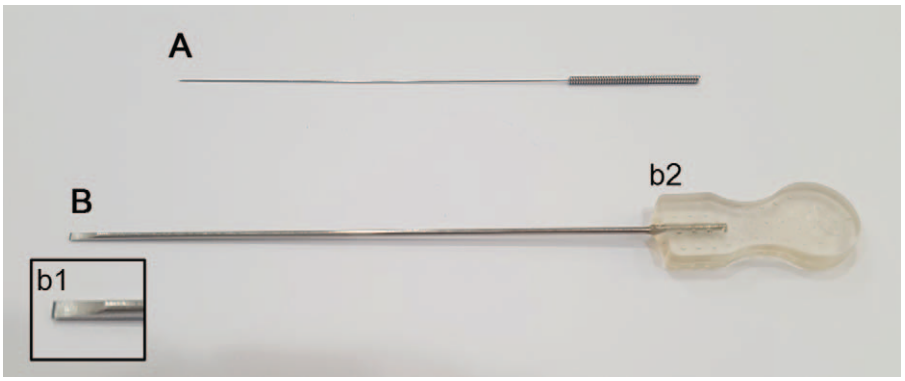

Figure 1. Conventional acupuncture needle and acupotomy. A, filiform needle (Dongbang Medical Co., Bo-ryung, Korea); 0.25 mm × 60 mm. B, acupotomy needle (Dongbang Medical Co., Bo-ryung, Korea), 1.0 mm × 80 mm; b1, the tip of an acupotomy needle; b2, the handle of an acupotomy needle.

1. Introduction

Lumbar spinal stenosis (LSS) is a disorder caused by compression of neural elements due to narrowing of the lumbar spinal canal or neural foramen. LSS is mainly caused by degenerative changes in the lumbar spine, with a prevalence that increases with age. The condition is frequently treated using spinal surgery.[1,2] A longitudinal population-based cohort study estimated that the prevalence of degenerative LSS (≤10 mm of the spinal canal) was 4.0% in individuals less than 40 years old, which increased to 19.4% in the 60 to 69 years old.[3] Although individuals with radiographically diagnosed LSS do not always experience clinical symptoms,[4] symptomatic LSS can present with neurogenic claudication, impaired walking, low back pain (LBP), and locomotive syndrome.[5,6] According to a cohort study of clinical progression of LSS over an 11-year period, 60% of patients who received conservative treatment did not experience worsened symptoms, although symptoms worsened in patients with a dural sac cross-sectional area of <50 mm^2.[7]

Physical therapy, exercise, and surgical interventions are standard treatments for LSS. Among these, the use of surgery for LSS has increased sharply[1,8]; however, recent spinal surgeries, such as decompression and spinal fusion, have been reported to be associated with a high rate of post-operative complications,[9,10] and comparatively low long-term satisfaction.[11,12] More importantly, the prevalence of postoperative "failed back surgery syndrome" has also increased, prompting clinicians and patients to seek more effective and safe treatment options.[13] Therefore, minimally invasive procedures for treating LSS has gained attention.[14,15]

Acupotomy, also called needle-knife or mini-scalpel needle acupuncture,[16] is a modernized form of acupuncture that combines a conventional acupuncture needle and a small scalpel, and can be considered as minimally invasive surgery (Fig. 1). The treatment with a knife-attached needle originates from the "Nine Classical Needles" of Huangdi Internal Classic (Huangdi Internal Classic, *Huang Di Nei Jing*); Zhu Hanzhang developed this treatment into the modern acupotomy procedure in 1976.[17] Recently, acupotomy has been applied to musculoskeletal disorders, particularly in China and the Republic of Korea. Clinical evidence has demonstrated that this treatment can decrease muscular spasm, and relieve compressed vessels and nerves by using the mini-scalpel to detach taut bands of muscle.[18] Additionally, in a network meta-analysis evaluating the efficacy of different techniques of acupuncture in myofascial pain syndrome, acupotomy improved the pressure-pain threshold more than did manual acupuncture, electro-acupuncture, dry-needling, acupuncture point injection, and fire-needle acupuncture.[19] Similarly, it has been reported that acupotomy may relieve pain and improve the quality of life in patients with degenerative LSS[20].

Given these characteristics, acupotomy may have different effects on LSS than conventional acupuncture[21,22]; in particular, the efficacy and safety profile may differ as it has greater invasiveness than acupuncture, but lower invasiveness than surgery. Because of the limitations of conventional treatments for LSS,[9–13] establishing evidence of the efficacy and safety of new treatment options, such as acupotomy, is important for both clinicians and patients. Therefore, this review was conducted to analyze the current evidence of the efficacy and safety of acupotomy in LSS.

2. Methods

This review was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[23] The protocol was published and registered in PROSPERO (registration number, CRD42018116567).[24]

2.1. Data sources and search strategy

We comprehensively searched the following English, Korean, and Chinese databases from their inception to December 28, 2018: Medline (via PubMed), the Cochrane Central Register of Controlled Trials [CENTRAL], EMBASE (via Elsevier), Allied and Complementary Medicine Database [AMED] (via EBSCO), Cumulative Index to Nursing and Allied Health Literature [CINAHL] (via EBSCO), Oriental Medicine Advanced Searching Integrated System [OASIS], Research Information Service System [RISS], Korea Citation Index [KCI], China National Knowledge Infrastructure [CNKI], Wanfang Data, and VIP. In addition, we searched the reference lists of the relevant articles and Google Scholar to identify additional trials. There were no restrictions on language and publication type, such as journal article and gray literature (theses and conference proceedings). The search strategy for each database is shown in Supplementary Material 1, http://links.lww.com/MD/D167.

2.2. Inclusion criteria

2.2.1. Types of studies. We included randomized controlled trials (RCTs) and excluded quasi-RCTs, using a quasi-randomization method, such as alternate allocation or allocation by birth date. If the expression "randomization" (randomization) was mentioned without description of the randomization methods, the study was included. We included parallel as well as crossover studies. Other designs, such as in vivo studies, in vitro studies, case reports, and retrospective studies, were excluded.

2.2.2. Participants. Studies involving patients with a diagnosis of LSS were included, regardless of sex, age, race, or severity and duration of disease. We excluded studies that included participants suffering from other serious illnesses, such as cancer, liver disease, or kidney disease.

2.2.3. Interventions. Studies using acupotomy as the experimental intervention, and wait-list, sham treatment, or active controls, such as acupuncture, physiotherapy, and nerve block, as control intervention were included. We included studies involving acupotomy combined with other therapies if the other therapies were equally used in both the experimental and control groups. Studies comparing different forms of acupotomy were excluded.

2.2.4. Types of outcome measures. The primary outcomes were

(1) LBP symptoms, measured using a visual analogue scale (VAS)[25] and Japanese Orthopedic Association (JOA) score,[26] and
(2) functional outcomes, measured using the Oswestry Disability Index (ODI).[27]

The secondary outcomes were total effective rate (TER), health-related quality of life, the incidence of adverse events, and amount of rescue medication required. TER is a non-validated outcome measure that is processed secondarily according to certain evaluation criteria, such as clinical symptom improvement or the rate of improvement in other quantified outcomes. Participants were generally classified as "cured" (cured), "markedly improved" (markedly improved), "improved" (improved), or "non-responder" (non-responder) after treatment, and TER was calculated consistently using the following formula: $TER = N1 + N2 + N3/N$, where $N1$, $N2$, $N3$, and N are the number of patients who are cured, markedly improved, and improved, and the total sample size, respectively.

2.3. Study selection

After removing duplicate studies, 2 researchers (CYK and BL) independently screened the titles and abstracts of the identified studies for preliminary inclusion. Then, they reviewed the full texts of the selected studies for final inclusion. Any disagreement was resolved by discussion with other researchers (JTL and SHY).

2.4. Data extraction

Using pre-defined data collection forms (in Excel 2007; Microsoft, Redmond, WA), 2 researchers (CYK and SHY) extracted data from the included studies. The extracted items included the name of the first author; publication year; country; approval by the relevant institutional review board; informed consent; sample size and number of dropouts; details about the participants, intervention, and comparisons; duration of the intervention; outcome measures; results; and adverse events. We extracted details of acupotomy, such as the stimulation site, needle type, anesthesia, and texture or sensation taken as indicating proper procedure, according to the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA).[28] We contacted the corresponding authors of the included studies via e-mail to request additional information if the data were insufficient or ambiguous.

2.5. Risk-of-bias assessment

Two researchers (CYK and BL) assessed the risk-of-bias of the included studies using the Cochrane group's risk-of-bias tool,[29] and any disagreement was resolved through discussion. The following items were evaluated as being "low risk," "unclear," or "high risk": random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, completeness of outcome data, selective reporting, and other sources of bias. We assessed other bias domains with particular emphasis on baseline imbalances between experimental and control group characteristics, such as mean age, sex, or disease severity, as these factors can cause bias in the estimation of the intervention effect.

2.6. Data analysis

We conducted descriptive analyses of the details of the participants, interventions, and outcomes for all included studies. Using Review Manager version 5.3 software (Cochrane, London, UK), we performed a meta-analysis across studies using the same types of intervention, comparisons, and outcome measures. We pooled continuous data, using the mean difference (MD) with 95% confidence intervals (CIs), and dichotomous data, using the risk ratio (RR) with 95% CIs. Heterogeneity among studies was assessed by the chi-squared test and the I-squared statistic; an I^2 value $\geq$50% indicated substantial heterogeneity and an I^2 value $\geq$75% indicated considerable heterogeneity. The random-effects model was used in cases of significant heterogeneity ($I^2 \geq 50\%$); otherwise, a fixed-effects model was used. The fixed-effects model was also used when the number of studies included in the meta-analysis was less than 5, where inter-study variance resulted in poor precision.[30,31] Subgroup analyses were performed according to

(1) the treatment period;
(2) severity of LSS, and
(3) type of active controls, such as acupuncture, physiotherapy, and nerve block.

We also performed sensitivity analyses by excluding

(1) studies with high risk-of-bias and
(2) outliers that were numerically distant from the rest of the data, to establish the robustness of the meta-analysis results.

Publication bias was assessed using funnel plots if more than 10 studies were included in the meta-analysis.

3. Results

3.1. Study description

The database searches identified 383 documents after removing duplicated publications. No additional studies were identified through other sources. After initial screening, the full texts of 39 articles were reviewed. Consequently, 7 RCTs[32–38] involving 429 participants were finally included in this review and meta-analysis (Fig. 2).

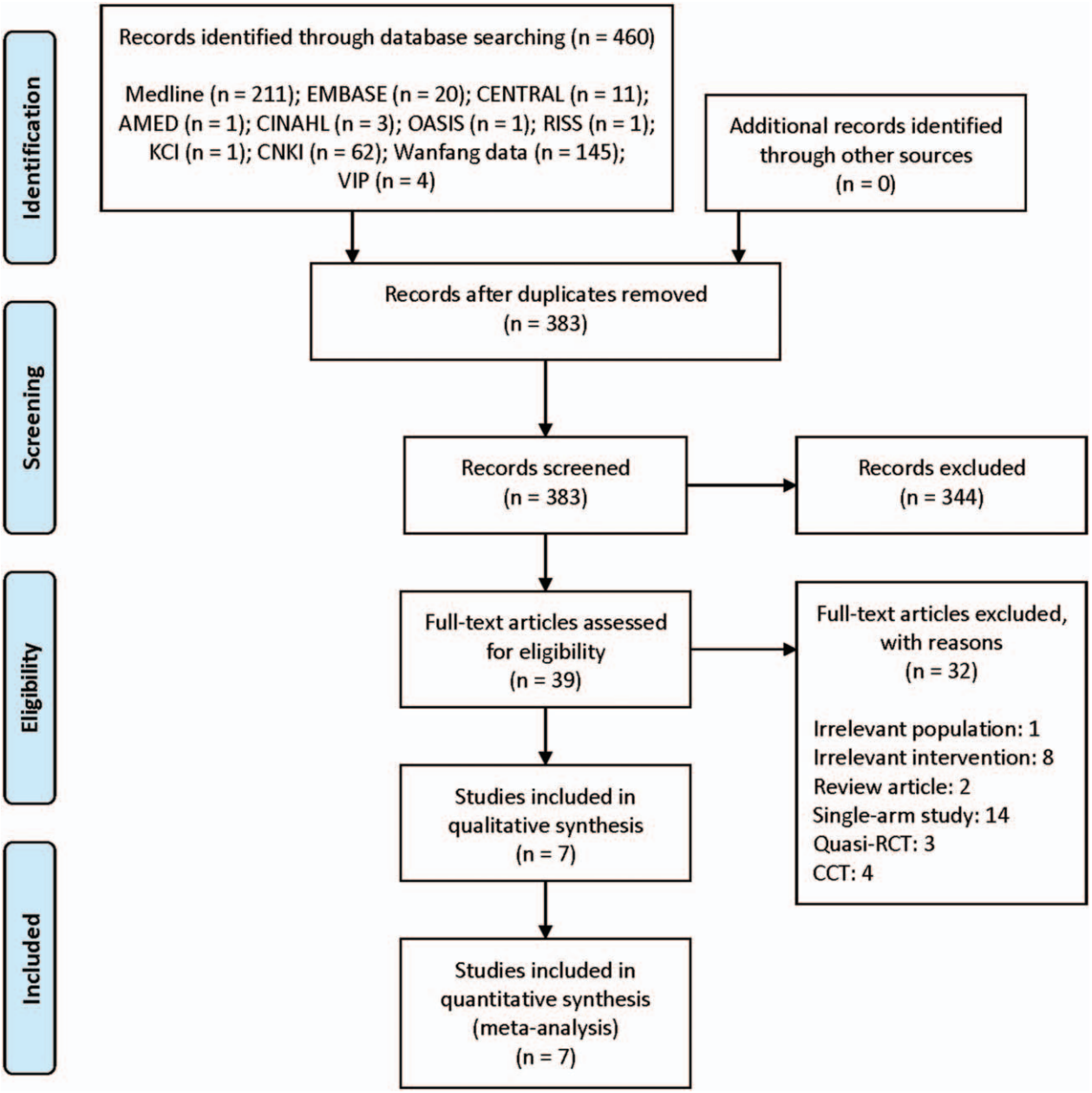

Figure 2. Flow chart of study inclusion.

3.2. Study characteristics

All included RCTs[32–38] had been published in China from 2009 to 2017; these included 5 journal articles, 1 dissertation, and 1 conference paper. The sample size ranged from 26 to 80, with a median of 60. The mean age of participants varied from 39 to 74 years. All RCTs were parallel studies with active controls, 6[32–37] of which were 2-arm parallel studies, and the remaining study[38] was a 4-arm parallel study. Two,[32,33] 3,[34–36] and 1[37] 2-arm parallel studies compared acupotomy with lumbar traction, spinal decompression, and acupuncture, respectively. The 4-arm parallel study[38] compared acupotomy vs percutaneous radiofrequency thermocoagulation (RFT) vs acupotomy combined with RFT vs spinal decompression. All studies included symptomatic LSS patients, and 4 studies[32,34,35,37] reported relevant textbook- or guideline-based diagnostic criteria. Except for 1 study[33] that used X-ray only, studies used computed tomography (CT) and/or myelography as well as X-ray for diagnosis of LSS.

One to 8 sessions of acupotomy were performed, with a median of 2 sessions. Seven,[32–38] 5,[33,35–38] and 3[33,35,37] studies reported TER, VAS, and JOA scores as outcomes. In addition, Sheng and Ni[33] reported serum levels $CD3^+$, $CD4^+$, and $CD8^+$, and $CD4^+/CD8^+$ ratio; Liu and Liu[34] reported the pain reduction rate; and Zhong et al[38] reported the operation time, intraoperative blood loss, X-ray irradiation time, and average number of hospital visits after surgery. Safety data were reported in only 1 study (Table 1).

Table 1

Characteristics of included studies.

Study	Sample size (included →analyzed)	Mean age (range)	Population	Mean disease period (range)	Treatment intervention	Control intervention	Outcome	Results	Adverse events
Acupotomy vs lumbar traction									
Ma[32]	80(40:40)→80(40:40)	TG: 61.6 (54-72) CG: 60.9 (51-71)	LSS[a,b0,c0,d1,e]	TG: NR (2m-17y) CG: NR (2m-18y)	Acupotomy (1session per 7–15 days, 3–4 sessions = 1 course, total 2 courses, 20 days between the courses)	Lumbar traction (1 session per day, 10 sessions = 1 course, total 4 courses, 3 days between the courses)	1) TER (pain, function)[$]	1) TG>CG+	NR
Sheng [33]	80(40:40)→80(40:40)	TG: 63.5±2.7 (60-75) CG: 63.8±3.0 (60-76)	LSS[b1,d2,e]	TG: 7.1±2.0m (4-12m) CG: 7.4±2.2m (5-14m)	Acupotomy (1 session per day, 3 sessions = 1 course, total 2 courses, 7 days between the courses)	Lumbar traction (1 session per day, 10 sessions = 1 course, total 4 courses, 3 days between the courses)	1) TER (pain, function) [$] 2) VAS[$] 3) JOA[$] 4) CD3+[$] 5) CD4+[$] 6) CD8+[$] 7) CD4+/CD8+[$]	1) TG>CG[*] 2) TG<CG[*] 3) TG>CG[*] 4) N.S. 5) TG>CG[*] 6) TG<CG[*] 7) TG>CG[*]	NR
Acupotomy vs spinal decompression									
Liu[34]	60(30:30)→60(30:30)	TG: 40.5±12.5 (NR) CG: 39.7±13.6 (NR)	LSS[a,b2,c2,d1,d2,e]	TG: 10.9±5.6y (NR) CG: 11.6±5.4y (NR)	Acupotomy (1 session per week, 2 sessions=1 course, total 1 course)	Spinal decompression (1 session per week, 2 sessions=1 course, total 1 course)	1) Totally pain reduction[$] 2) TER (pain, function)[$]	1) TG>CG[*] 2) TG>CG[*]	NR
Su[35]	75(38:37)→75(38:37)	TG: 60.3 (47-70) CG: 59.5 (45-70)	LSS[a,b0,c0,d1,e]	TG: 5.4y (3-20) CG: 5.2y (3-19)	Acupotomy (1 session per week, 3 sessions=1 course, total 1 course)	Spinal decompression (1 session per week, 3 sessions=1 course, total 1 course)	1) VAS[$] 2) JOA[$] 3) TER (pain, function) (1y f/u)	1) TG<CG[*] 2) TG>CG[*] 3) TG>CG[*]	NR
Wu[36]	26(13:13)→26(13:13)	TG: 48.8±3.7 (39-70) CG: 58.2±2.5 (40-69)	LSS[b1,c1,d1,d2,e]	TG: 6.2±2.4y (2-10) CG: 7.1±3.6y (3-12)	Acupotomy (1 session)	Spinal decompression (1 session)	1) TER (pain, function) 2) VAS (1m, 3m, 6m f/u)	1) TG>CG[*] 2) TG<CG[*] (1m, 3m, 6m f/u)	NR
Acupotomy vs acupuncture									
Zhang[37]	60(30:30)→60(30:30)	TG: 54.50±8.80 (40-75) CG: 56.43±8.70 (42-77)	LSS[a,b1,c1,d2,e]	TG: 10.00±4.41y (3-20) CG: 9.30±4.15y (2-15)	Acupotomy (1 session per week, 2 sessions=1 course, total 1 course)	Acupuncture (1 session per day, 7 sessions=1 course, total 1 course)	1) VAS[$] 2) JOA[$] 3) TER (pain, function) [$]	1) TG<CG[*] 2) TG>CG+ 3) N.S.	Not occurred
Acupotomy vs acupotomy+RFT vs RFT vs spinal decompression									
Zhong[38]	48(12:12:12:12)→48(12:12:12:12)	74.0±9.1 (NR)	LSS[b2,c2,e]	NR	TG1(B): Acupotomy (1session) TG2(C): Acupotomy +RFT (1 session)	CG1(A): RFT (1 session) CG2(D) Spinal decompression (1 session)	1) operation time (min) 2) intraoperative blood loss (ml) 3) X-ray irradiation time(sec) 4) average number of hospital visits after surgery (day) 5) VAS (1m f/u, 6m f/u, 12m f/u) 6) TER(JOA)(12m f/u)	1) A, B, C<D[*] 2) A, B, C<D[*] 3) A, B, C>D+ 4) A, B, C<D[*] 5) A, B<D[*] (1, 6, 12m f/u); C<A, B[*] (6, 12m f/u); otherwise, N.S. 6) N.S.	NR

'[*]' and '+' mean significant differences between 2 groups, $P > .05$ and $P > .01$, respectively. 'N.S' means no significant difference between 2 groups, $P > .05$. '[$]' means that the time of measurement is post-treatment.

CG = control group; JOA = Japanese Orthopaedic Association; LSS = Lumbar spinal stenosis; NR = not recorded; RFT = percutaneous radiofrequency thermocoagulation; TER = total effective rate; TG = treatment group; VAS = visual analogue scale.

a. relevant textbook or guideline

b0. XR, with no specific criteria

b1. XR: ≤15 mm of spinal canal

b2. XR: <13 mm of spinal canal

b3. XR: ≤12 mm of spinal canal

c0. CT or myelography, with no specific criteria

c1. CT or myelography: ≤100 mm^2 of cross-sectional area of spinal canal, ≤4 mm of lateral recess

c2. myelography: ≤3 mm of lateral recess

d1. lumbar hyperextension test (positive)

d2. SLR test (both positive and negative results were allowed)

e. history of clinical symptoms including chronic low back pain, intermittent claudication, etc.

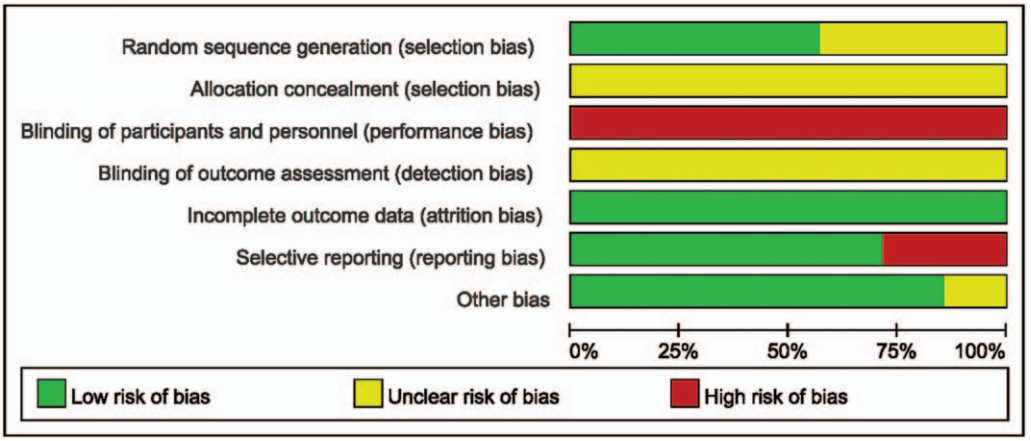

Figure 3. Risk-of-bias in the included studies.

3.3. Risk-of-bias assessment

Except for the 3 studies[32,34,35] that did not mention the random sequence generation method, the 4 studies[33,36–38] reporting appropriate randomization methods were assessed to have a low risk-of-bias in the random sequence generation domain. No studies reported on allocation concealment and blinding of participants, personnel, and outcome assessment. However, considering the invasive nature of acupotomy, which makes it difficult to blind, all studies were assessed to have a high risk-of-bias in terms of blinding of the participants and personnel. There were no dropouts or withdrawals of participants in any of the studies. Two studies[32,34] that reported only on TER, a secondary processed form of data, as outcome measure were assessed to have a high risk-of-bias in the selective reporting domain. Except for 1 study[38] that did not report statistical homogeneity in the characteristics of participants between the groups at baseline, 6 studies[32–37] were assessed as having a low risk-of-bias in other source of bias domains (Figs. 3 and 4).

3.4. Efficacy and safety of acupotomy for LSS

Meta-analysis was performed on VAS, JOA, and TER outcomes at the last evaluation in each study, based on 5, 3, and 7 studies, respectively. Subgroup analysis was performed according to the type of active controls used.

3.4.1. Primary outcomes: VAS, JOA. Based on the pooled results, acupotomy was associated with a significantly lower VAS score (VAS score ranging from 1 to 10) as compared with active controls (5 RCTs; MD −1.55, 95% CI −2.60 to −0.50; I^2 = 94%). In subgroup analysis according to the type of active controls used, the significant benefits of acupotomy remained when compared to lumbar traction (1 RCT; MD −1.33, 95% CI −1.80 to −0.86) and acupuncture (1 RCT; MD −1.57, 95% CI −2.11 to −1.03). However, there were no significant differences between both groups when acupotomy compared to spinal decompression (3 RCTs; MD −2.36, 95% CI −4.81 to 0.09; I^2 = 97%) and RFT (1 RCT; MD 1.90, 95% CI −0.41 to 4.21) (Fig. 5).

Zhong et al[38] reported that a group in which acupotomy was combined with RFT had significantly lower VAS pain scores at

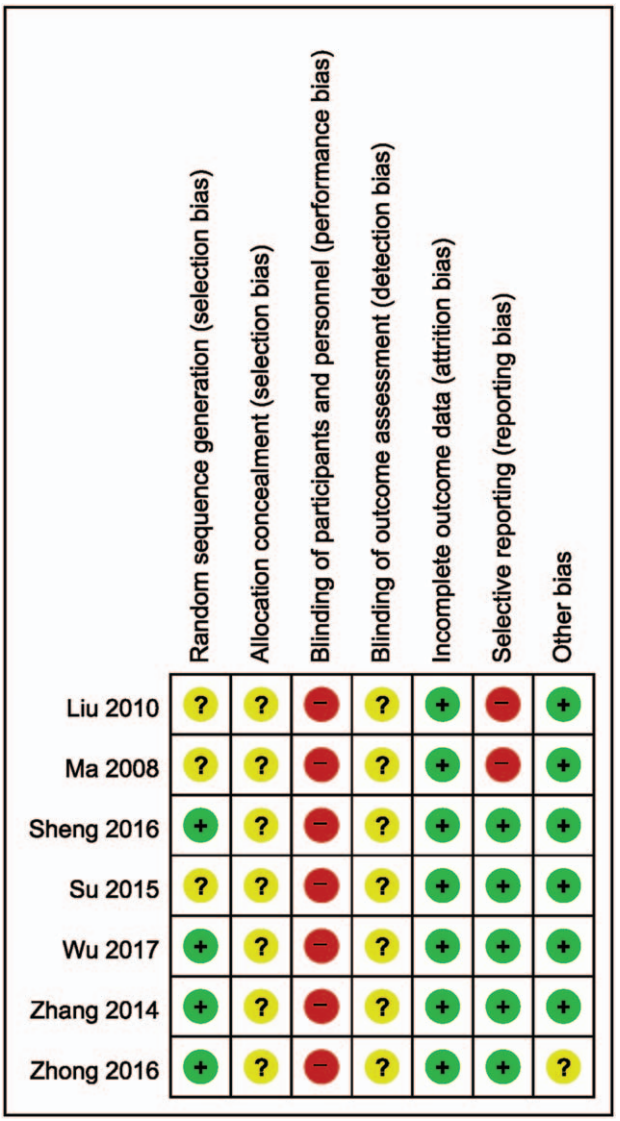

Figure 4. Risk-of-bias summary.

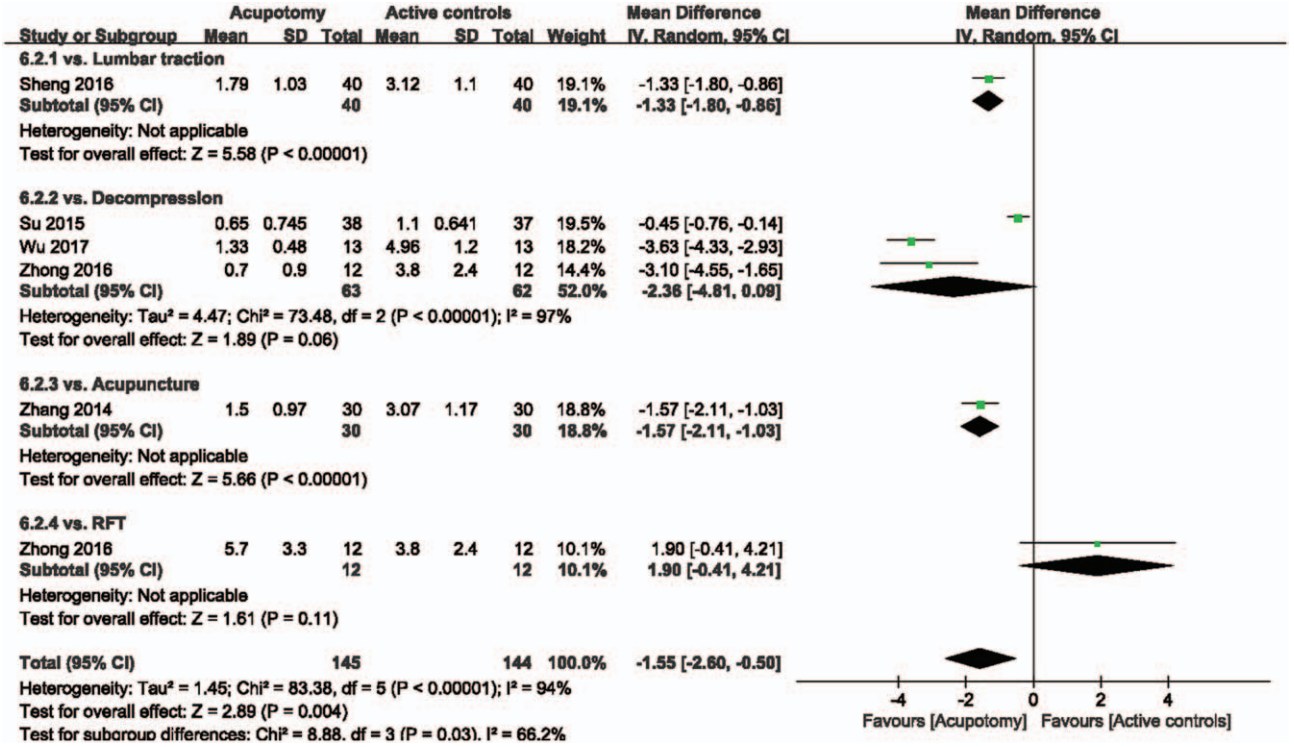

Figure 5. Forest plots of visual analogue scale (VAS). Comparison: Acupotomy vs Active controls. Subgroup analysis according to the types of active controls used.

the 12-months follow-up, as compared to the RFT group ($P < .001$); however, there was no significant difference between the combined group and the spinal decompression group ($P > .05$).

According to the pooled results, acupotomy was associated with a significantly higher JOA score than the active controls, with no heterogeneity among studies (3 RCTs; MD 4.70, 95% CI 3.73 to 5.68; $I^2 = 0\%$). The significant benefits of acupotomy remained in all subgroup analyses based on the type of active controls, (1 RCT for lumbar traction, MD 4.29, 95% CI 2.51 to 6.07; 1 RCT for spinal decompression, MD 5.16, 95% CI 3.84 to 6.48; 1 RCT for acupuncture, MD 3.90, 95% CI 1.42 to 6.38) (Fig. 6).

3.4.2. Secondary outcome: TER. According to the pooled results, acupotomy was associated with a significantly higher TER than the active control treatment, without significant heterogeneity among studies (7 RCTs; RR 1.19, 95% CI 1.09 to 1.29; $I^2 = 24\%$). In subgroup analysis according to the type of active controls, the significant benefits of acupotomy remained when compared to lumbar traction (2 RCTs; RR 1.23, 95% CI 1.07 to 1.41; $I^2 = 0\%$) and spinal decompression (4 RCTs; RR 1.23, 95% CI 1.08 to 1.40; $I^2 = 44\%$). However, there were no significant differences when acupotomy was compared to acupuncture (1 RCT, RR 1.08, 95% CI 0.88 to 1.32) and RFT (1 RCT, RR 0.91, 95% CI 0.67 to 1.23) (Fig. 7).

Zhong et al[38] reported that there were no significant benefits of acupotomy combined with RFT in terms of TER at the 12-months follow-up, as compared to RFT only and spinal decompression (both $P > .05$).

3.4.3. Other measures of efficacy. Sheng and Ni,[33] comparing acupotomy with lumbar traction, reported that acupotomy was associated with a significantly higher serum level of $CD4^+$ and a higher $CD4^+/CD8^+$ ratio, and significantly lower $CD8^+$ level (all $P < .05$). There was no significant difference between the groups in terms of $CD3^+$ levels ($P > .05$). Liu and Liu,[34] comparing acupotomy with spinal decompression, reported that acupotomy was associated with a significantly higher rate of pain reduction ($P < .05$). Zhong et al,[38] who compared acupotomy vs RFT vs acupotomy combined with RFT vs spinal decompression, reported that spinal decompression was associated with a significantly longer operation time, intraoperative blood loss, and greater average number of hospital visits after surgery, than the other 3 treatments (all $P < .05$). In their study, the spinal decompression group was also associated with significantly lower radiation exposure time in X-ray imaging than the other 3 groups (all $P < .01$); there were no other significant differences found among the groups.

3.4.4. Safety. Only 1 study, by Zhang,[37] who compared acupotomy with acupuncture, reported on adverse events related to the interventions; there was no adverse event that occurred during that study.

3.5. Analysis of the acupotomy procedure

Overall, acupotomy was performed in 1 to 2 treatment courses, with 1 to 3 treatment sessions per course. Two RCTs[32,33] conducted 2 treatment courses, with rest periods of 20 days and 7 days, respectively, between courses. In all studies, the lumbar area was considered to be the treatment area, and in 1 study, both the

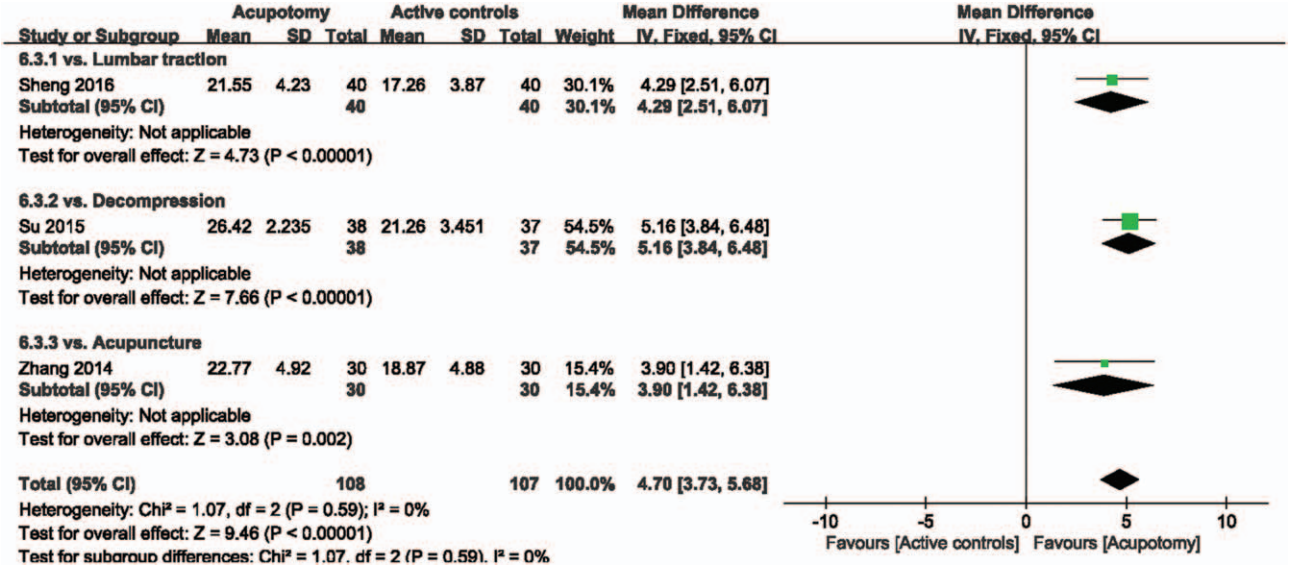

Figure 6. Forest plots of Japanese Orthopedic Association (JOA) score. Comparison: Acupotomy vs Active controls. Subgroup analysis according to the types of active controls used.

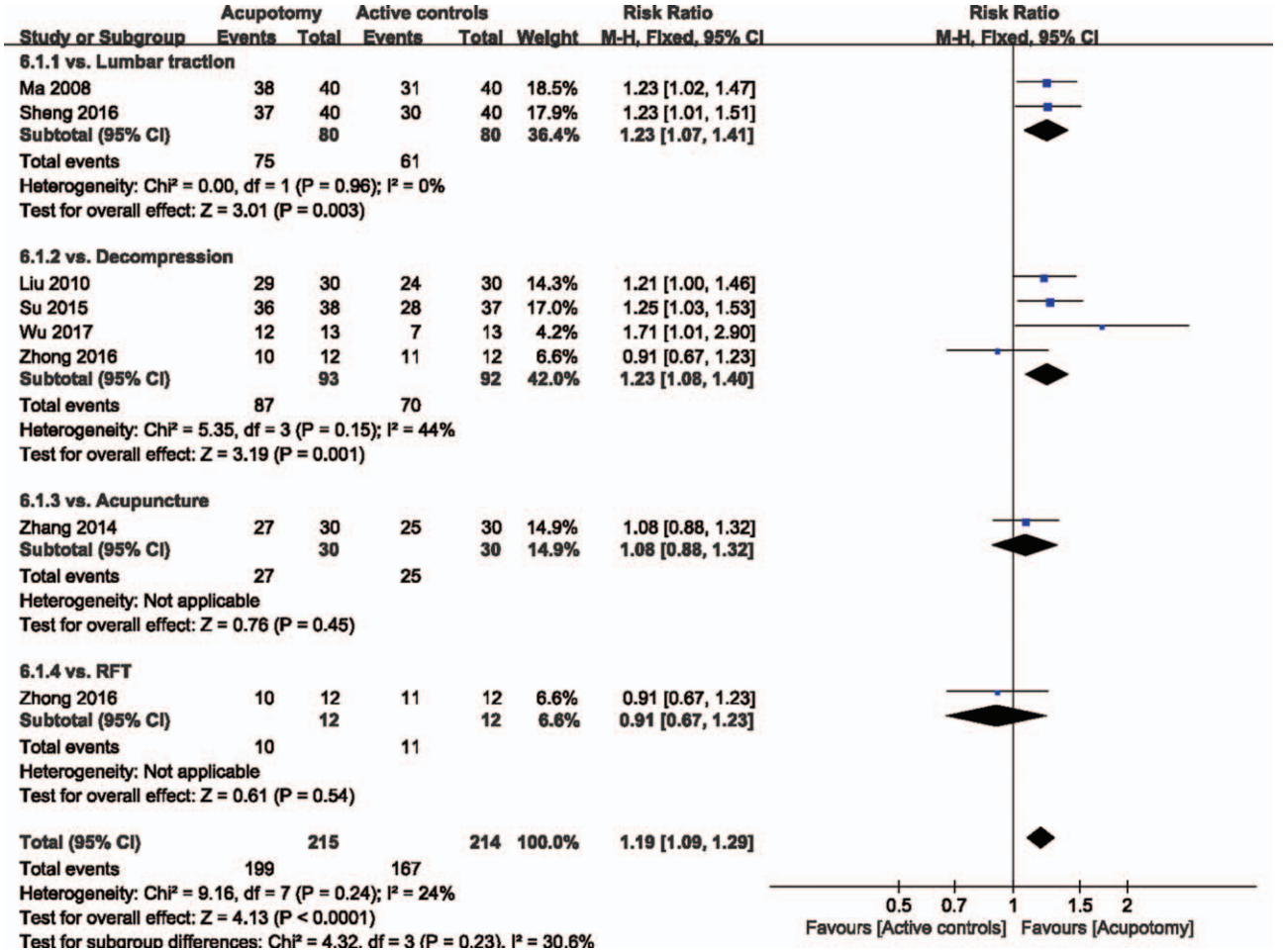

Figure 7. Forest plots of total effective rate (TER). Comparison: Acupotomy vs Active controls. Subgroup analysis according to the types of active controls used.

Table 2

Acupotomy treatment methods for LSS.

	Number of needles	Treatment points	Depth of insertion	Texture indicating proper procedure	Needle retention time	Needle type	Total treatment course	Frequency (rest period between the courses)	Other interventions	Qualifications or experiences	Control intervention
Acupotomy vs lumbar traction											
Ma[32]	NR	tender points of lumbar facet joint, transverse process, spinous process, sacrum, glutaeus medius, piriformis, tensor fasciae latae, iliac crest, ischial tuberosity, tender points of lower leg	level of muscle to bone surface	NR	no retention	NR	2courses	3-4sessions/course, 1session/7-15d (20d)	N/A	NR	lumbar traction
Sheng[33]	NR	interlaminar space, lumbar nerve root	level of nerve root	contractured texture	no retention	NR	2courses	3sessions/course, 1session/d (7d)	N/A	NR	lumbar traction
Acupotomy vs spinal decompression											
Liu[34]	NR	interlaminar space, lumbar nerve root	level of nerve root	contractured texture	no retention	NR	1course	2sessions/course, 1session/w	N/A	NR	spinal decompression
Su[35]	4	Erector spinae muscles, facet joint, yellow ligament, lumbar nerve root	level of muscle to nerve root	contractured, adhered texture	no retention	needle with rounded blade, capable of injection	1course	3sessions/course, 1session/w	injection (saline, lidocaine,neurotropin, and triamcinolone acetonide)	NR	spinal decompression
Wu[36]	NR	interlaminar space, lumbar nerve root	level of nerve root	NR	no retention	NR	1course	1session/course	N/A	NR	spinal decompression
Acupotomy vs acupuncture											
Zhang[37]	NR	interlaminar space, yellow ligament	level of yellow ligament	NR	no retention	knife edge diameter 0.8mm; length 210mm	1course	2sessions/course, 1session/w	N/A	NR	acupuncture
Acupotomy vs acupotomy+RFT vs RFT vs spinal decompression											
Zhong[38]	NR	interspinous process, spinous process, tip of transverse process, medial branch of the lumbar dorsal ramus, interlaminar space, yellow ligament	level of yellow ligament	NR	no retention	needle diameter 1mm; knife edge diameter 0.8mm; length 80mm	1course	1session/course	with or without RFT	NR	RFT or spinal decompression

LSS = Lumbar spinal stenosis; N/A = not applicable; NR = not recorded; RFT = percutaneous radiofrequency thermocoagulation.

lumbar area and tender points of the lower legs were treated. The most frequently treated area in the lumbar region was the interlaminar space in 5 studies,[33,34,36–38] followed by the lumbar nerve root in 4 studies,[33–36] and the yellow ligament in 3 studies.[35,37,38] One study[35] reported the number of needles (n = 4 needles) used. The insertion depth of the needle was mostly described as the levels of the nerve root or the yellow ligament.[35–38] All 3 studies[33–35] that reported on texture indicating appropriate procedure indicated a contracture texture. No studies used needle retention. No studies described the qualifications or experience of practitioners (Table 2).

3.6. Publication bias

The publication bias could not be assessed because only 7 studies were included in this review.

4. Discussion

In this comprehensive review, we conducted a meta-analysis of 7 RCTs[32–38] to evaluate the efficacy and safety of acupotomy for LSS. The results suggested that acupotomy treatment was associated with significantly lower VAS than the active controls. However, in subgroup analysis, this significance remained only in comparisons against lumbar traction and acupuncture, while no significant differences were noted in comparisons against spinal decompression or RFT. For the JOA score, the acupotomy treatment group had significantly higher JOA scores than the active control groups. In subgroup analysis, acupotomy showed significant superiority to lumbar traction, spinal decompression, as well as acupuncture. In terms of secondary outcomes, acupotomy treatment was associated with a significantly higher TER than the active control treatments. However, according to subgroup analysis, this significance remained only when acupotomy was compared with lumbar traction and spinal decompression, but not in comparison with acupuncture or RFT. Safety data were reported in only a single study; no adverse events occurred in either the acupotomy group or acupuncture control group.

LSS is currently a major problem, resulting in high socioeconomic costs and high surgical rates.[1–3,8] In order to overcome the limitation of existing surgical approaches,[9–13] minimally invasive approaches have been considered,[14,15] and acupotomy is a minimally invasive technique that combines the effects of conventional acupuncture with micro-incision. In a network meta-analysis, acupotomy was reported to be superior to other acupuncture methods in improving the pressure-pain threshold in myofascial pain syndrome.[19] In animal studies, acupotomy has been shown to have anti-inflammatory and anti-nociceptive effects,[39,40] and to have a greater protective effect against continuous cell damage than electro-acupuncture.[41,42] More importantly, the LBP guidelines published by the China Association of Acupuncture-Moxibustion recommended acupotomy for adventitial changes in lumbar soft tissues, such as muscles, ligaments, and the articular capsule.[43] We therefore performed a comprehensive review of the efficacy and safety of acupotomy as a new approach for treating LSS.

Our results suggested that acupotomy may have efficacy equivalent to or better than that of other active controls in treating LSS. However, the study had some limitations. First, the most important limitation is that the results of the comparison with each active control were mostly based on a single small RCT, which reduces the confidence in the results, and suggests the possibility of small-study effects. Second, we could not perform subgroup analysis according to the planned treatment duration, given the marked heterogeneity of the frequency of acupotomy treatment, despite similar overall treatment duration. In addition, subgroup analysis according to severity could not be performed because no useful information was provided for the objective classification of the severity of the condition at baseline. Third, the methodological quality of the included studies was generally poor. This means that our results are likely to change significantly in subsequent studies. Fourth, because only a small number of studies were included, we could not evaluate publication bias using funnel plots. All included studies were conducted in China, and, given the small-study effects mentioned above, the possibility of publication bias in our results is not negligible. Fifth, the reports of acupotomy procedures in the included studies were insufficient and were not standardized. As acupotomy is more invasive than conventional acupuncture, the experience and qualifications of the practitioner are very important; nevertheless, none of the studies reported on this matter. Finally, accurate assessment of the value of acupotomy requires robust evidence of its safety as well as efficacy. However, with the exception of 1 study, the studies did not report safety data. Therefore, we could not conclude the safety of acupotomy as a treatment for LSS.

In future, larger RCTs based on rigorous methodology should be implemented. In particular, rigorous reporting of acupotomy procedures and safety data is needed. The acupotomy procedure should be reported in accordance with STRICTA guidelines.[28] Safety studies of acupotomy are currently underway in China and Korea[44–46]; thus, future researchers will be able to refer to these studies. Considering the limitations of the surgical approach for LSS, it is necessary to evaluate whether the rate of surgery for LSS patients undergoing acupotomy is changing, by national cohort studies assessing health insurance claim data. These data will determine whether acupotomy, a minimally invasive approach, can be a new alternative to the surgical approach. Although animal studies have reported on the mechanism underlying acupotomy, including its anti-inflammatory and anti-nociceptive effects, further efforts are needed to elucidate the mechanism by which this treatment exerts effects in LSS.

5. Conclusion

According to the current evidence, acupotomy might be beneficial for treating LSS. Acupotomy showed a consistent superiority over lumbar traction, but results were mixed for other interventions, such as spinal decompression and acupuncture. However, the findings should be interpreted with marked caution, due to the poor methodological quality of the included studies, and potential small-study effects. Additional large-sample, high-quality, rigorous RCTs should be conducted and acupotomy procedures and safety data should be rigorously reported.

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