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Acupotomy for Superior Cluneal Nerve Entrapment Syndrome: A Review of Randomized Controlled Trials

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This review aims to analyze the efficacy of acupotomy in treating superior cluneal nerve entrapment syndrome (SCNES) by summarizing the findings of randomized controlled trials (RCTs). The RCTs were retrieved from seven databases (i.e., the Cochrane Library, PubMed, Embase, China National Knowledge Infrastructure, Korean Studies Information Service System, Research Information Service System, and Oriental Medicine Advanced Searching Integrated System). Seven RCTs were selected for this review. The results indicate that acupotomy is promising for providing significant pain relief and improving function in patients with SCNES. However, more high-quality RCTs are required to establish the long-term effectiveness and safety of acupotomy. This review provides valuable insights for clinicians and researchers in the management of SCNES.

Keywords: Acupotomy; Nerve entrapment; Randomized controlled trial

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INTRODUCTION

Superior cluneal nerve entrapment syndrome (SCNES) is characterized by pain in the lower back, groin, leg, or foot because of entrapment of the superior cluneal nerves. This neuropathic condition has been recently emphasized, and studies have found a wide variation in estimates of the incidence of low back and leg pain caused by superior cluneal nerve dysfunction, ranging from 1.6% to 14%. Current treatments include a spectrum of interventions, ranging from pharmacological management with medications to physiotherapy, chiropractic, injections, manual therapies, and acupuncture [1]. Acupotomy, which merges acupuncture principles with minimally invasive surgical techniques, has emerged as an alternative therapy that directly addresses nerve decompression. The procedure uses a specialized flat-edged needle to dissect and separate adhesions within the pathological tissues [2]. The origin of acupotomy dates back to the 1990s in China, and it was designed for its simplicity of execution and minimization of treatment duration compared with that with surgery. It promotes circulation and relieves pain by resolving muscular and connective tissue adhesions without the concern of open wound scarring, thereby reducing the risk of infection [3]. Our study aimed to evaluate randomized controlled trials (RCTs) of acupotomy used in the management of SCNES. We aspire to create a comprehensive database that can locally inform upcoming clinical trials, which will allow for the development of a more organized method of using acupotomy as a treatment choice for this syndrome. This review assesses the clinical effectiveness of acupotomy in managing SCNES as reported in RCTs.

MATERIALS AND METHODS

1. Inclusion and exclusion criteria

To be considered for this review, studies must meet the following specific criteria:

- Enrollment of individuals affirmed to have SCNES as determined by clinical diagnosis.
- The RCT designated acupotomy exclusively as the intervention for the group under treatment.
- Studies were excluded from this review under the following circumstances:
- Previously published or duplicated research.
- Nonrandomized or observational studies.
- Studies in which the full text was unavailable.
- Research not subjected to peer-review processes.
- Studies diverging from the primary focus on acupotomy or the syndrome in question.

Restrictions were not imposed on the publication language, publication date, provenance, or participant demographics.

2. Database and search strategy

The search canvased the literature released until February 20, 2024. Databases examined included the Cochrane Library, PubMed, Embase, China National Knowledge Infrastructure (CNKI), Korean Studies Information Service System (KISS), Research Information Service System (RISS), and Oriental Medicine Advanced Searching Integrated System (OASIS). Keywords were selected to capture studies pertinent to both SCNES and acupotomy interventions, ensuring a comprehensive review. The keywords chosen for the search were “Superior Cluneal Nerve Entrapment Syndrome” and “acupotomy.”

3. Evaluation of the study quality

The integrity and dependability of the study findings were evaluated through a structured bias assessment. Two impartial reviewers appraised the included trials using the Cochrane risk of bias (RoB) 2.0 framework. This instrument evaluates potential biases from the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result [4]. Any assessment discrepancies were resolved through discussion with a supervising researcher or intervention by a neutral external party.

RESULTS

1. Selection of studies

Our comprehensive search through multiple databases yielded 55 individual studies. After initial screening, the search yielded 1 study in the Cochrane Library, 5 studies in PubMed, 1 study in Embase, 48 studies in the CNKI, 0 studies in the KISS, 0 studies in the RISS, and 0 studies in the OASIS. Subsequent filtering led to the exclusion of four duplicates. The next search removed additional studies: 29 were not RCTs and 10 were found in nonscientific journals. Of the 12 remaining studies, one was excluded because it did not directly pertain to the topic of acupotomy. Four studies were excluded from consideration because they involved mixed interventions within the treatment groups, which could confound the effects of acupotomy. This selection process ultimately identi-

fied seven studies suitable for inclusion in our final analysis (Fig. 1).

2. Evaluation of the risk of bias

The RoB in the included studies was meticulously analyzed using the Cochrane RoB 2.0 tool, and the findings were graphically represented (Figs. 2, 3).

1) Bias arising from the randomization process

All studies [5-11] exhibited "some concern" according to the RoB 2.0 tool because of the incomplete description of the randomization methods.

2) Bias due to deviations from the intended intervention

All studies [5-11] were rated as "low" RoB because they provided clear descriptions of the interventions and reported any deviations from the intended protocol.

3) Bias due to missing outcome data

All studies [5-11] were rated as "low" RoB in this domain because they provided clear explanations for any missing outcome data and conducted appropriate statistical analyses accounting for the missing data.

4) Bias in measurement of the outcome

All studies [5-11] were rated as "high" RoB because measurement of the outcomes was not entirely blinded, introducing potential bias in outcome assessment.

5) Bias in the selection of reported results

One study [9] was rated as "low" RoB; however, others [5-8,10,11] were rated as "high" RoB because not all specified outcomes were reported in the study findings.

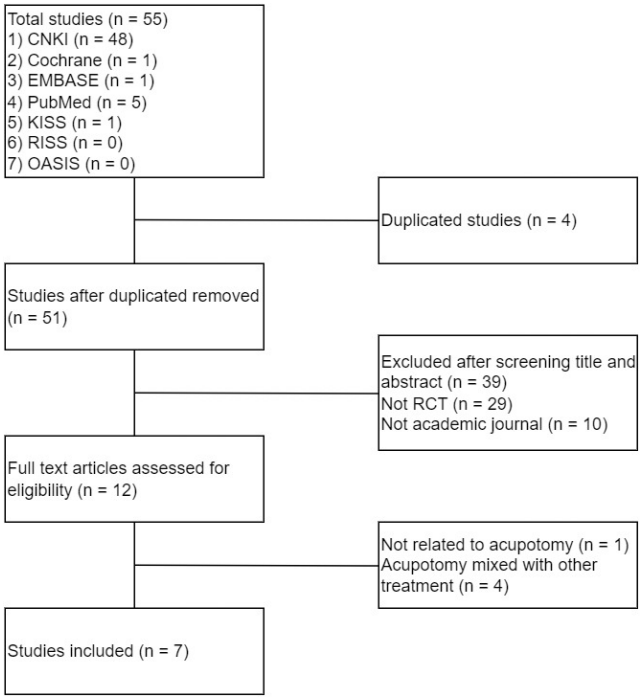

Fig. 1. Flow diagram of the study selection process. RCT, randomized controlled trial.

3. Overview of the included studies

The seven selected RCTs, published until 2024, were all retrieved from the CNKI. The RCTs were all conducted in China and reported in Chinese. In total, 520 participants with SCNES were included in the seven RCTs. The study with the most participants comprised 120 individuals, whereas the study with the fewest participants comprised 20 individuals.

The inclusion and exclusion criteria were applied in all seven studies. In five papers [5-8,10], the diagnosis of SCNES was commonly based on the following characteristic symptoms:

- The patient has pain or numbness on the affected side of the buttocks, which may reflect the lateral posterior side of the thigh, with or without a history of trauma.
- There is apparent local tenderness; sometimes, a stripe-like object can be felt with distinct pain upon palpation.

Two papers [9,11] did not provide specific information on the diagnostic criteria for SCNES. The general characteristics of the treatment and control groups were

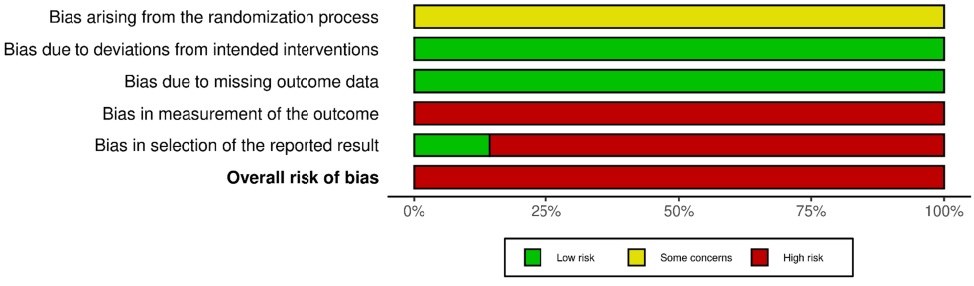

Fig. 2. Risk of bias (RoB) summary based on the Cochrane RoB 2.0 tool.

comparable and exhibited no statistically significant differences (Table 1).

4. Interventions in the selected studies

The selected studies used acupotomy as the primary treatment intervention for SCNES. Hua et al. [5] used regular acupuncture as a control group, and one study used a filiform fire needle. Three studies [8,9,11] used only electroacupuncture as a control group. Li et al. [6] involved two control groups: one using electroacupuncture and the other using in-row multi-needling. Luo and Tang [7] used electroacupuncture with moxibustion. Acupotomy was commonly performed once a week, and the treatment period differed from 1 day to 9 weeks. In three studies [7-9], type I No. 3 acupotomy needles were used, whereas two studies [6,11] used Han brand No. 3 acupotomy needles. Hua et al. [5] used a specification of 0.35 × 0.35 × 75-mm acupotomy needles, and Yao [11] used a 0.60 × 75-mm acupotomy needle. Only one study [5] clarified the treatment time as 10–20 minutes per treatment. One study [10] defined the insertion depth as < 5 mm, whereas other studies did not specify the insertion depth. Six studies [5-8,10,11] used targeted treatment points as cord or tender points, and the specific points varied among the studies. None of the studies defined specific traditional acupoints for treating SCNES.

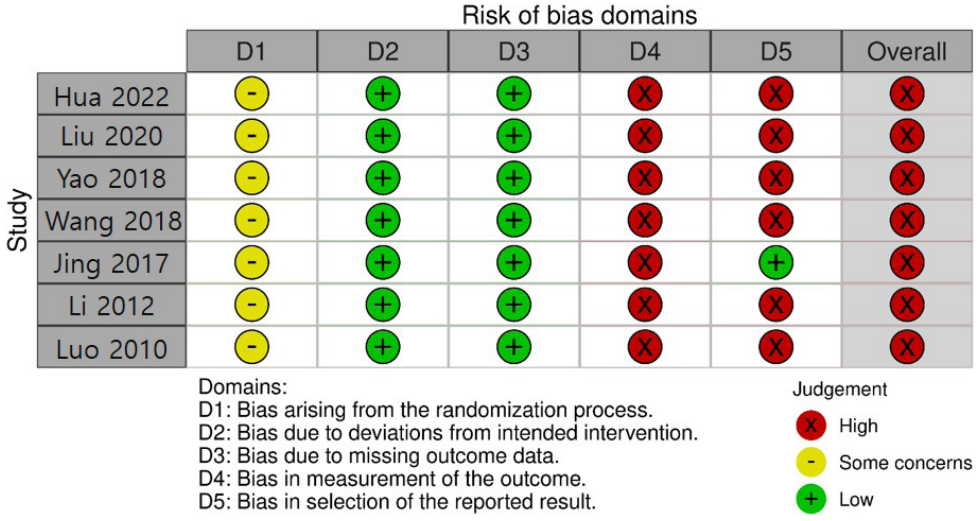

Fig. 3. Risk of bias (RoB) graph based on the Cochrane RoB 2.0 tool.

Table 1. Overview of the included studies

Author (y)	Type	Sample size	Age (y)	Course
Hua (2022) [5]	RCT	TG 60 CG 60	TG (48.37 ± 13.87) CG (48.98 ± 12.75)	10.00–71.50 (30.00) d 13.00–68.50 (31.00) d
Liu (2020) [10]	RCT	TG 30 CG 30	TG (53.3 ± 8.1) CG (52.9 ± 8.0)	(2.21 ± 1.92) y (2.72 ± 1.47) y
Yao (2018) [11]	RCT	TG 10 CG 10	TG 40–75 (57.6 ± 4.0) CG 41–76 (58.7 ± 4.3)	NR
Wang (2018) [8]	RCT	TG 25 CG 25	TG 25–60 (38.6 ± 3.4) CG 27–61 (39.2 ± 3.6)	4 wk–3 y (1.2 ± 0.5) y 3 wk–3 y (1.1 ± 0.4) y
Jing (2017) [9]	RCT	TG 35 CG 35	TG 22–77 (49.5 ± 5.2) CG 21–74 (47.5 ± 3.5)	2–12 (7.0 ± 1.2) mo 2–11 (6.5 ± 1.1) mo
Li (2012) [6]	RCT	TG 40 CGa 40 CGb 40	TG 33–72 (46 ± 5) CG1 34–67 (47 ± 5) CG2 31–69 (46 ± 6)	3.5–143.0 (23.8 ± 4.3) mo 4.0–125.0 (24.3 ± 3.4) mo 1.5–121.0 (24.7 ± 4.7) mo
Luo (2010) [7]	RCT	TG 48 CG 32	TG 26–59 (37.6) CG 28–62 (38.2)	1 d–8 y 1 d–8 y

Values are presented as range (mean ± standard deviation).
RCT, randomized controlled trial; TG, treatment group; CG, control group; CGa, control group a; CGb, control group b; NR, not reported.

Four studies [7-10] targeted the third lumbar transverse process as a treatment point. The acupotomy treatments mainly focused on the adhesiolysis process or targeted cord-like tender points.

5. Assessment indicators

In assessing the effectiveness of treatments, the effective rate was the most used indicator, which reflects the degree of improvement compared with baseline values. Five studies [7-11] assessed three outcomes: cure, improvement, and invalidity. Li et al. [6] measured three other outcomes: remarkable effect, improvement, and invalidity. Hua et al. [5] specified four indicators: cure, significant impact, improvement, and invalidity. Most studies [5,8-11] assessed the effectiveness rate by cure–improvement case/total case; however, one study [6] reported a remarkable effect rate as statistically significant. Luo and Tang [7] did not report the real efficacy rate as significant but reported the cure rate as significant.

Two studies [5,6] used numeric rating scales (NRSs) to assess pain intensity before and after treatment. In Hua et al. [5], the NRS scores gradually decreased in the treatment group compared with those in the control group and were significantly lower after treatment. Li et al. [6] showed that after 2 and 4 weeks of treatment, the NRS scores in the acupotomy group were significantly lower than those in the electroacupuncture group. However, after 4 weeks of treatment, the in-row multinee-

Table 2. Interventions and results of the selected studies

Author (y)	Intervention	Control	Outcome measurement	Results
Hua (2022) [5]	Acupotomy	Filiform fire needle	1. Effective rate 2. NRS 3. ADL-BI 4. Holden walking ability scale	1. TG 96.67% > CG 81.67% ($p < 0.05$) 2. TG < CG ($p < 0.05$) a: TG 2.68 ± 1.11 < CG 3.23 ± 1.11 ($p < 0.05$) b: TG 1.67 ± 0.99 < CG 2.50 ± 1.02 ($p < 0.001$) c: TG 0.00 (1.00) < CG 1.00 (2.00) ($p < 0.05$) 3. TG > CG ($p < 0.05$) a: TG 77.50 ± 13.20 < CG 72.58 ± 14.04 ($p < 0.05$) b: TG 90.75 ± 9.99 < CG 81.25 ± 12.51 ($p < 0.001$) c: TG 96.92 ± 9.30 < CG 90.75 ± 11.12 ($p < 0.05$) 4. TG > CG ($p < 0.05$) a: TG 3.38 ± 0.99 > CG 2.93 ± 1.02 ($p < 0.05$) b: TG 4.25 ± 0.82 > CG 3.60 ± 0.83 ($p < 0.001$) c: TG 4.88 ± 0.45 > CG 4.88 ± 0.45 ($p < 0.001$)
Liu (2020) [10]	Acupotomy	Acupuncture	1. Effective rate 2. VAS	1. TG 93.33% > CG 66.67% ($p < 0.05$) 2. TG 1.78 ± 1.22 < CG 2.44 ± 1.30 ($p < 0.05$)
Yao (2018) [11]	Acupotomy	Electroacupuncture	1. Effective rate 2. JOA	1. TG 90% > CG 80% ($p < 0.05$) 2. TG 26.8 ± 1.4 > CG 20.9 ± 3.0 ($p < 0.05$)
Wang (2018) [8]	Acupotomy	Electroacupuncture	1. Effective rate 2. Lumbar function rating scale	1. TG 92% > CG 68% ($p < 0.05$) 2. TG 21.35 ± 5.22 > CG 18.11 ± 4.21 ($p < 0.05$)
Jing (2017) [9]	Acupotomy	Electroacupuncture	1. Effective rate 2. VAS	1. TG 94.29% > CG 80.00% ($p < 0.05$) 2. TG 1.02 ± 0.11 < CG 1.68 ± 0.22 ($p < 0.05$)
Li (2012) [6]	Acupotomy	CGa: in-row multi-needling CGb: electroacupuncture	1. Effective rate 2. NRS 3. Patient satisfaction	1. 2 wk: TG 62.5% > CGb 25.0% ($p < 0.05$) 4 wk: CGa 90.0% > TG 67.5% ($p < 0.05$) CGa 90.0% > CGb 35.0% ($p < 0.05$) TG 67.5% > CGb 35.0% ($p < 0.05$) 2. 2 wk: TG 2.4 ± 0.9 < CGb 3.6 ± 0.6 ($p < 0.05$) 4 wk: TG 2.2 ± 0.8 < CGb 3.1 ± 0.6 ($p < 0.05$) CGa 0.9 ± 0.5 < CGb 3.1 ± 0.6 ($p < 0.05$) CGa 0.9 ± 0.5 < TG 2.2 ± 0.8 ($p < 0.05$) 3. CGa > TG ($p < 0.05$) CGa > CGb ($p < 0.05$)
Luo (2010) [7]	Acupotomy	Electroacupuncture + moxibustion	Effective rate	TG 52.1% > CG 21.9% ($p < 0.01$)

NRS, numeric rating scale; ADL-BI, activities of daily living Barthel index; TG, treatment group; CG, control group; VAS, visual analog scale; JOA, Japanese orthopedic association score; CGa, control group a; CGb, control group b; NR, not reported.

Table 3. Details of the acupotomy

Author (y)	Period	Frequency	Number of treatments	Treatment points	Acupotomy needle	Depth of insertion	Treatment Time
Hua (2022) [5]	9 d	1/3 d	3	Cord-like tender points on: Thoracolumbar fascia Tensor fascia lata Gluteus medius muscle Origin of the gluteus maximus muscle	0.35 (w) × 0.35 (d) × 75 (l) mm	NR	10–20 min
Liu (2020) [10]	4 wk	1/wk	4	Cord-like points on: L3 transverse process Trigger point within 10 cm from the hip to the midline and more than 2.5 cm below the Iliac crest	0.60 (d) × 75 (l) mm	Less than 5 mm	NR
Yao (2018) [11]	1 d	1/d	1	Tender point or node at 2–3 cm below the midpoint of the iliac crest	Han brand no. 3	NR	NR
Wang (2018) [8]	9 wk	1/wk	9	Cord-like points on: L3 transverse process Center of the iliac crest 3 cm before and after the center of the iliac crest	Type I no. 3	NR	NR
Jing (2017) [9]	2 wk	1/wk	2	The apex of the upper edge of the L3 transverse process	Type I no. 3	NR	NR
Li (2012) [6]	4 wk	1/wk	4	The center of the area with apparent tenderness, discomfort, or local muscle elasticity and shape change	Han brand no. 3	NR	NR
Luo (2010) [7]	3 wk	1/wk	3	The endpoint of the L3 transverse process and iliac crest point Ashi acupoint	Type I no. 3	NR	NR

w, width; d, diameter; l, length; NR, not reported.

dling group exhibited significant efficiency compared with the acupotomy or electroacupuncture group.

One study [5] used the activities of daily living Barthel index (ADL-BI) and the Holden walking ability scale. As treatment continued, the ADL-BI of the treatment group gradually decreased compared with that of the control group and showed a significant difference. The Holden walking ability scale increased compared with that in the control group, indicating an improvement in walking ability. Two studies used a visual analog scale (VAS). In Jing et al. [9] and Liu [10], the VAS scores of the treatment group decreased compared with those of the control group, indicating a decrease in pain intensity. One [11] study used the Japanese orthopedic association score (JOA) to evaluate the neurological function of patients with superior cluneal nerve entrapment and to assess improvements in lumbar function. The JOA showed significantly improved lumbar function in the treatment group compared with that in the control group.

Wang and Yi [8] used their lumbar score to assess the overall improvement in lumbar function, which includes four evaluation indicators: subjective symptoms (9 points), objective signs (6 points), limitations in daily life activities (14 points), and bladder function (6 points). The maximum score for the evaluation is 35. The study showed an increase in lumbar function scores in the treatment group compared with that in the control group, indicating an overall improvement in lumbar function.

Li et al. [6] rated patient satisfaction as quite satisfied, somewhat satisfied, satisfied, dissatisfied, or very dissatisfied. They showed that patient satisfaction of the in-row multi-needling group was slightly significant compared with that in the acupotomy or electroacupuncture group (Tables 2, 3).

DISCUSSION

The superior cluneal nerve comprises the cutaneous branches of the posterior rami of the T11–L5 nerve roots. It passes through the thoracolumbar fascia and the superior rim of the iliac crest. When the nerve is compressed, pain occurs in the lower back and upper buttocks, causing SCNES. The response to the injection mainly diagnoses it. SCNES is usually misdiagnosed and can be degenerated [12], presenting with tenderness on the middle portion of the posterior iliac crest with pain radiating to

the proximal gluteal region. SCNES is mainly treated with nerve blocks or surgical releases [13]. It is known to be diagnosed clinically by palpating tender points along the iliac crest and reproducing the characteristics of buttock pain or by performing diagnostic injections. Nerve block, alcohol neurolysis, peripheral nerve stimulation, and surgical decompression are known treatments for SCNES [14].

Acupotomy is a type of acupuncture that uses a blade-needle combined surgical scalpel at the tip of the needle. It is a minimally invasive treatment method with a simple operation method, short treatment time, and low risk of tissue damage and infection compared with surgical treatment. It has been widely used as a treatment for various musculoskeletal diseases because it has the effects of traditional acupuncture, such as stripping adhesions and releasing contractures [2,15].

Our study included seven studies from seven databases based on our inclusion criteria that compared acupotomy with traditional acupuncture and electroacupuncture. In the overview of the included studies, it was evident that most RCTs were conducted in China and published in Chinese. The sample size across the studies varied, with the most extensive study comprising 120 participants and the smallest comprising 20 individuals. The diagnostic criteria for superior cluneal nerve entrapment were consistent in five studies, whereas two studies [9,11] did not provide specific information on the diagnostic criteria. The general characteristics of the treatment and control groups were comparable across the included studies, indicating a level of consistency in the baseline characteristics of the participants.

The interventions used in the selected studies primarily focused on acupotomy as the primary treatment for SCNES, with variations in the control groups and treatment protocols. Acupotomy was administered once a week, with treatment periods ranging from 1 day to 9 weeks. The specific acupotomy needles and treatment parameters varied across the studies, reflecting a lack of standardization in the intervention protocols. Furthermore, the targeted treatment points varied among the studies, and no specific traditional acupoints for SCNES treatment were defined.

When assessing the effectiveness of the treatments, the effective rate reported by patients immediately after treatment was the most used indicator across the studies. However, the specific outcome measures and assessment methods varied, with some studies employing NRS, VAS, and JOA scores and patient satisfaction ratings. Although these indicators provided insights into the impact of the interventions on pain intensity and overall satisfaction, the varied assessment methods made it challenging to directly compare the outcomes across the studies. Li et al. [6] showed that acupotomy had a more short-term effect on SCNES; however, in the in-row multi-needling group, the treatment had more long-term effects. Based on this, in-row multi-needling may be superior to acupotomy; however, more research is required. None of the studies mentioned adverse effects or abnormal reactions within the treatment or control groups.

Based on this research, acupotomy is effective for the management of SCNES. However, this study has limitations. Most studies had similarities in that they targeted cord-like tender points with acupotomy. Because the treatment point was not agreed upon, the effects of the treatment could vary among the study implementers. A standardized version of acupotomy treatment must be developed for future studies to accurately evaluate its impact. In the future, standardized assessment indicators would be beneficial for assessing the efficacy of acupotomy and comparing it with traditional acupuncture and electroacupuncture for the treatment of SCNES. Further research with consistent assessment methods will provide a more comprehensive understanding of the potential benefits of acupotomy in clinical practice. To assess the safety of acupotomy, more research should be conducted on the adverse effects or abnormal reactions compared with other interventions. The assessment of the RoB in the included studies suggests that the overall RoB is high. Although the studies provided clear descriptions of the interventions and accounted for missing outcome data, there were limitations in the blinding of outcome assessments and the selection of reported results. Higher-grade RCTs should be conducted to have more validity regarding acupotomy for the treatment of SCNES. The randomization process should be described in detail, and a method for blind acupotomy with other treatments should be devised. The included studies provided valuable insights into the use of acupotomy for the treatment of SCNES. Future research should aim to address these limitations and establish more robust evidence for the effectiveness of acupotomy in the management of SCNES.

CONCLUSION

The findings from the selected studies highlight the potential of acupotomy as an effective intervention for the management of SCNES. The evidence supports the

positive outcomes associated with acupotomy treatment, including reductions in pain intensity, improvements in walking ability, and overall enhancement in lumbar function. Furthermore, patient satisfaction with acupotomy was notably significant compared with that with other interventions. Future research efforts should aim to further validate the findings and explore the optimal application of acupotomy in the management of SCNES. This will contribute to a more comprehensive understanding of the role of acupotomy in clinical practice and ensure its evidence-based integration into the management of SCNES.

AUTHOR CONTRIBUTIONS

Conceptualization: HMK. Data curation: HMK, YKL. Formal analysis: HMK, YKL. Investigation: HMK, YKL. Methodology: HMK, YKL. Project administration: HMK. Supervision: YKL. Writing – original draft: HMK. Writing – review & editing: HMK, JSK, HJL, JHL, SCL, YKL.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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None.

ETHICAL STATEMENT

This research did not involve any human or animal experiments.

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