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Review Article

Analysis of Clinical Research Trends for Thread Embedding Acupuncture of Cervical Radiculopathy

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ABSTRACT

In this study, the evidence of thread embedding acupuncture (TEA) in treating cervical radiculopathy in randomized controlled trials was investigated. We searched 16 databases up to August 22, 2022. Of the 2,644 studies retrieved, 22 randomized controlled trials (2,483 participants) were selected. Quality assessments were performed using Cochrane's risk-of-bias tool and RevMan 5.4 software. Outcome measures in the included studies typically showed TEA had a significant therapeutic effect compared with simple acupuncture and other remedies, and TEA was better than sham TEA. Catgut and polydioxanone had no difference in effectiveness, however, catgut was considered to be less safe. TEA was shown to be more therapeutic when inserted deeper into the skin. Ultrasound guided TEA was more effective and safer than conventional TEA, and using a flat blade needle was better than conventional needles for TEA. No serious adverse events were reported from using TEA, and only a few mild side effects were observed. However, the limited number and heterogeneity of the included studies, together with the unclear methodological quality, indicate that higher-quality studies need to be conducted to determine the effectiveness and safety of TEA for cervical radiculopathy.

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Introduction

Cervical radiculopathy (CR) is a group of signs and symptoms indicating compression of the cervical spinal nerve root [1], and it is associated with numbness, pain, loss of sensation, and can seriously affect quality of life [2]. The prevalence of CR has previously been reported to range from 1.07 to 1.76 per 1,000 for males, and 0.63 to 5.8 per 1,000 for females, and peaks in the 4th and 5th decades in life [3,4]. It was reported last year that with changes in people's work and lifestyles, the incidence of CR has increased [5].

Treatment guidelines recommend: surgery, traction, medication, massage, acupuncture, moxibustion, and/or physical therapy [6]. In the last decade there has been an increased rate in surgery for CR, however, there is no accurate indication for surgical CR [7]. In addition, 4% of patients who undergo surgery suffer postoperative side effects [8]. Without surgery, more than 75% of patients' symptoms significantly improve within three months of conservative treatment [7]. Among the conservative methods used in clinical practice to treat CR, thread embedding acupuncture (TEA) is one of the most effective and is attracting attention in Korea [9].

The principle of TEA is based on the theory of acupuncture and moxibustion and is where thread continuously stimulates the acupoint where it has been embedded. The threads used stimulate

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tissues (such as skin, muscles, ligaments, and tendons) to induce an immune reaction to treat the patient's condition. TEA is useful for various conditions/diseases that require long-term acupoint stimulation, especially neurogenic, musculoskeletal, and visceral pain-related conditions/diseases [10]. However, despite the use of TEA treatment for CR in clinical trials, few studies have reviewed the treatment effects of TEA for CR. A systematic review of TEA for CR was conducted in 2020 in China [11], but with a limited selection of literature, little analysis and minimal quality evaluation. In this study, to determine a consensus for the direction of clinical research on TEA for CR, clinical effectiveness and safety were evaluated by analyzing the acupoints, tools, and embedding methods used.

Materials and Methods

Search strategy

There were 16 databases searched, including 4 English language databases (PubMed, EMBASE, Cochrane Library, and Google Scholar), 2 Chinese databases [China National Knowledge Infrastructure (CNKI) and the Wanfang databases], 2 Japanese databases (CiNii and J-stage), and 8 Korean databases [KISS, ScienceOn, KMbase, KoreaMed, Koreascience (KISTI), OASIS, RISS, and Korean Traditional Knowledge Portal (KTKP)]. No restrictions on country, language, or publication date were imposed on the searches which were performed up to August 22, 2022.

In the international databases the following search terms were used: [("cervical" OR "neck") AND ("radiculopathy" OR "nerve root" OR "neck and arm pain") AND ("catgut" OR "thread" OR "needle" OR "acupuncture" OR "acupoints") AND ("implant*" OR "embed*" OR "embedding therapy" OR "maesun" OR "maeseon")]. In the Chinese and Japanese databases, the search terms were inputted in both English and Chinese/Japanese. In the domestic databases (assuming that there would be few studies) the search terms "maesun" or "maeseon" (which means TEA in Korean) were used. Different synonyms were combined to perform searches according to the characteristics of the database used.

Document screening and data extraction

Two researchers independently performed the search according to the inclusion and exclusion criteria and preliminary selection was made after reading the article titles and abstracts. Duplicates were removed, and the remaining articles full text was read to ensure relevant content.

The extracted content included items such as researchers, year of publication, number and gender ratio of treatment and control groups, mean duration of illness, intervention with two groups, outcome indicators, results, dropouts, and adverse events (AEs). Details of TEA and control interventions according to the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) [12] were also extracted.

In cases of disagreement, a 3rd researcher participated in discussion, consultation, and decision-making, and if necessary, contacted the authors of studies to obtain further information on the studies.

Eligibility criteria

The inclusion criteria were as follows: (1) Studies should be randomized controlled trials (RCTs) reported in domestic and foreign journals (we included RCTs with no specific delineation of the randomization methods referred to simply as "random allocation"); (2) studies on patients with CR, regardless of race, gender, or severity and duration of disease; (3) treatment groups treated with TEA (which could include interventions that differed from the control group, except for TEA, with no restrictions on control interventions); and (4) studies conducted in any country or language, with any publication date.

The exclusion criteria were as follows: (1) non-RCT, quasi-RCT, case report, and systematic review studies; (2) duplicate research, obvious data errors or data failure; (3) no use of a control group in the study design; (4) exclusion of needle embedding therapy, such as press-needle or intradermal acupuncture, if TEA was not performed on the treatment group; (5) exactly the same TEA conditions used for both treatment and control groups, making it impossible to compare the effects of TEA between groups; and (6) theses.

Quality assessment

Two reviewers independently evaluated the risk of bias in the selected literature. If no agreement was reached, a 3rd party intervened, and the decision was made by majority vote. The Cochrane's risk-of-bias tool (ROB) 2 was used as an evaluation tool for quality assessment and the NECA Systematic Literature Review Manual [13] was used as a reference. ROB 2 contains assessment fields that relate to "low risk," "unclear risk," or "high risk" of bias, including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other biases. If we applied random allocation but did not describe specific random methods, such as random number tables, computers, dice, or coin use, the output was an "unclear risk." For incomplete outcome data, if there was no mention of dropouts, but the criteria for elimination were presented, bias was deemed to be "low risk." Regarding reporting bias, if the presence or absence of adverse reactions was not mentioned, it also led to a determination of "unclear risk."

Results

Study search results

A total of 2,644 articles were retrieved from 16 databases. After eliminating 2,586 articles that did not meet the eligibility criteria, 34 duplicate records were also removed. Of the remaining 24 studies, 2 were excluded because they used the same TEA methods in both the treatment and control group. Twenty-two articles [14-35] were included in the final review (Fig. 1).

Basic characteristics of the studies

There were 22 studies included in the review which were

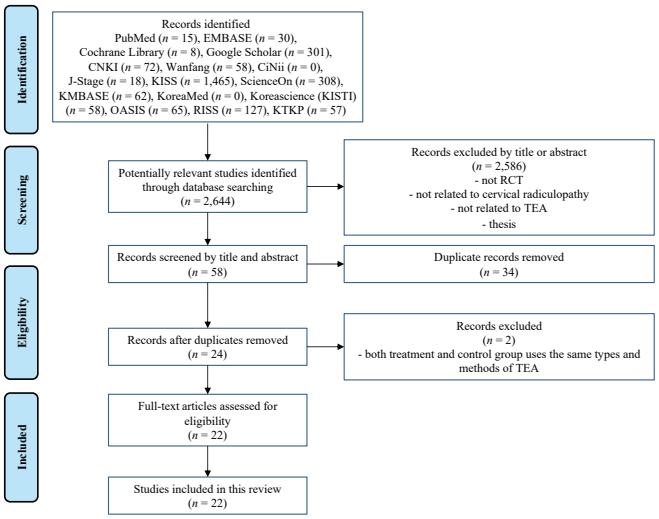

Fig. 1. Flow chart of document retrieval and screening.

published between 2010 and 2021. A total of 2,483 individuals were included in this review, and the characteristics of the studies are shown in Table 1 [14-35]. Each trial used between 60-360 patients. The gender distribution could not be determined due to some RCTs not reporting the gender ratio. The duration of CR symptoms ranged from 1 month to 9 years but duration was not reported in three studies. None of the studies differed significantly regarding general information such as sex ratio, age, and morbidity period between groups before treatment. Three studies experienced dropouts [14,21,30]. Thirty-five dropout cases were reported overall, including 21 in treatment groups and 14 in control groups. All trials were conducted in China of which, one study was written in English [14]. Four studies involved three-arm parallel trials [14,17,21,33], and the remainder all involved two-arm trials. All patients in the studies were diagnosed with CR.

Materials

The most frequently used materials in the studies were catgut (eight studies; [16-18,21,23,24,28,32]), followed by polyglycolide-lactide (PGLA; 7 studies; [14,15,26,27,29,33,34]), polydioxanone (PDO; 4 studies; [20-22,25]), chromic catgut (1 study: [19]), and collagen (1 study; [30]). Two studies [31,35] only mentioned the manufacturer of the absorbent surgical suture without specifying the material.

Size and length of the TEA tools

Regarding the size of the TEA tools, the range of thread length 0.5-3 cm, with an average of 1.3 cm. The most frequently used length was 1 cm. Two studies made no mention of thread length [16,19]. The thickness of the thread used was based on United States Pharmacopoeia (USP) monographs ranging from USP 4-0 to USP 2. The most frequently used thickness was USP 2-0 in eight studies, followed by USP 4-0 in seven studies.

Regarding the length of embedding needles, only two studies mentioned that used 4 cm [20] and 6.9 cm [29] needles the other studies did not mention the length of the needle used. A few studies explicitly mentioned the diameter of the needle, and most of them reported the standard numbers. The diameters of the needles were 0.3-0.9 mm, but most studies preferred 0.9 mm-diameter needles (No. 9 needles in 10 studies).

Treatment sites

The most frequently used acupoint in TEA was EX-B2, which was used in 18 of the 22 studies. Although two studies did not specify an acupoint, they used a local region near the cervical spine as a treatment site [17,24]. The remaining two studies expected a therapeutic effect from inserting medical threads into distal acupoints in the abdomen [23] or hand [30] without using local acupoints in the treatment group. The 2nd most used acupoint after EX-B2 was GV14, which was used in 13 studies. Ashi points were also used as local acupoints. The most used distal acupoints were BL12, LI4, LI11 (each used in five trials), followed by GB20, BL11, BL15, SI3, and GV20 (each used in four trials). Many of the studies used acupoints determined by pattern identification.

Treatment frequency and duration

The frequency of TEA was once every 7 to 15 days. The most common frequency was once a week [14,15,20,22,25,26,30,33,34], followed by once every 14-15 days [19,21,23,24,27,29,31,35] and every 10 days [16,17,32]. TEA was administered 2-4 times, and 2 times was the most frequent (10 studies), followed by 3 times (7 studies), and 4 times (3 studies). Two studies did not report the frequency or number of sessions. The total TEA treatment period was 2-6 weeks. The most common period was 28-30 days (9 studies), followed by 21-22 days (5 studies), 2 weeks (4 studies), 45 days (2 studies), and 6 weeks (1 study). One study did not specify the duration of treatment.

Outcome measures

Of the 22 studies, 18 studies used efficacy rates based on 3 or 4 criteria: full recovery, significant effect, moderate effect, and no effect (some studies did not use the "significant effect" category). Based on these criteria, they all reported total efficacy rates, meaning the percentage of the total minus the "no effect" cases. Full recovery rates were also reported [17-19]. The 2nd most frequently used outcome measure (applied in 16 studies) was the visual analog scale (VAS), which allows the patient to indicate on a scale of 0 to 10 the level of pain they are experiencing. Nine studies used the Neck Disability Index (NDI), seven used Yasuhisa Tanaka 20 (YT-20), four used the Pain Rating Index and Present Pain Index, and one study used the Northwick Park Neck Pain Questionnaire. Besides the above-mentioned evaluation indicators, some studies used measures such as the Short Form 36-Item Health Survey [14], analgesic effective rate [23], cervical range of motion [32], range of motion score [24], and symptom score [31], as shown in Table 2 [14-35].

Table 1. Characteristics of the Included Studies.

Study ID (author [y])	Sample size [enrolled→analyzed (male/female)]		Duration of CR (mean)		Treatment details of experimental group					Treatment details of control group		
	EG	CG	EG	CG	Materials	Thread size (length, USP)/ needle size (length and diameter)	TEA points	Concomitant treatment	Frequency, sessions, duration of treatment	Type of control	Treatment points	Frequency, sessions, duration of treatment
Comparison with sham TEA												
Chu YX (2018) [14]	MAPE 34→34 (9/25) 2 dropouts DAPE 34→34 (11/23) 3 dropouts	SHAE 34→34 (10/24) 5 dropouts	MAPE 56.5 mo DAPE 77.8 mo	SHAE 68.5 mo	PGLA	1.016 cm, NR/ NR, 0.0762 cm	* EX-B2 (C5-6), GV14, † SJ5, GB34, BL60, SI3, LI4, ST44, LR3, GB40 (with US, EX-B2 targets semispinalis capitis [MAPE], multifidus [DAPE])	-	1/1 wk, 3, 3 wk	Sham acupoint embedding	* EX-B2 (C5-6), GV14, † SJ5, GB34, BL60, SI3, LI4, ST44, LR3, GB40	1/1 wk, 3, 3 wk
Comparison of different TEA depths												
Sun WS (2015) [33]	SAPE 30 (9/21) MAPE 30 (6/24) DAPE 30 (7/23)		SAPE 5.3 y MAPE 4.9 y DAPE 4.5 y		PGLA	1 cm, No. 2-0/ NR, 0.9 mm	* EX-B2 (C5-6, affected side), GV14 † None (with US, EX-B2 targets subcutaneous [SAPE], semispinalis capitis [MAPE], multifidus [DAPE])	-	1/1 wk, 3, 3 wk			
Comparison of different TEA materials												
Feng H (2012) [21]	PDO 123→117 (69/48) Catgut 130→122 (67/55)	AT 107→98 (51/47)	PDO 30.6 mo Catgut 31.5 mo	AT 29.3 mo	PDO or catgut	PDO or catgut 1-3 cm, No. 4-0/ NR, 0.7 mm	* EX-B2 (affected level, both), BL11, BL12 † GB20, GV20, LI11, LI4, GV14, BL13, BL15 (same acupoint for PDO group and catgut group)	-	1/2 wk, 2, 2 wk	AT	* EX-B2 (affected level, both), BL11, BL12 † GB20, GV20, LI11, LI4, GV14, BL13, BL15	1/2 d, 15, 30 d
	Safety evaluation group 92 (48/44)		29.5 mo		PDO + catgut	PDO and catgut 1-2 cm, No. 4-0/ NR, NR	* EX-B2 (C3,5,7, both) † None (PDO on left, catgut on right)	-	Once, 1, 1 d			
Comparison of different TEA insertion methods												
Sun WS (2018) [34]	30 (10/20)	30 (13/17)	19.77 mo	19.83 mo	PGLA	1 cm, No. 2-0/ NR, 0.9 mm	* EX-B2 (C5-6) † None (with the US)	-	1/1 wk, 3, 3 wk	Conventional TEA (PGLA)	* EX-B2 (C5-6) † None (No US)	1/1 wk, 3, 3 wk

Table 1. (continued).

Study ID (author [y])	Sample size [enrolled→analyzed (male/female)]		Duration of CR (mean)		Treatment details of experimental group					Treatment details of control group		
	EG	CG	EG	CG	Materials	Thread size (length, USP)/ needle size (length and diameter)	TEA points	Concomitant treatment	Frequency, sessions, duration of treatment	Type of control	Treatment points	Frequency, sessions, duration of treatment
Comparison with acupuncture												
Sun WS (2013) [15]	45 (28/17)	45 (20/25)	5.7 y	4.9 y	PGLA	1 cm, No. 2-0/ NR, 0.9 mm	* EX-B2 (C4-7), GV14 † None	-	1/1 wk, 4, 4 wk	AT	* EX-B2 (C4-7), GV14 † None	1/1 d, 28, 4 wk
Qiu C (2015) [35]	63 (40/23)	63 (39/24)	30.mo	29.03 mo	NR	1 cm, No. 2-0/ NR, 0.9 mm	* EX-B2 (C3-7), GV14, GB21, LI11(all affected side) † None	-	1/2 wk, 3, 6 wk	AT	* EX-B2 (C3-7), GV14, GB21, LI11 (all affected side) † None	1/1 d, 30, 30-36 d
Li RQ (2015) [26]	43 (23/20)	43 (23/20)	5.1 y	5.6 y	PGLA	1 cm, No. 2-0/ NR, 0.9 mm	* EX-B2 (C4-7), GV14 † None	-	1/1 wk, 4, 4 wk	AT	* EX-B2 (C4-7), GV14 † None	1/1 d, 28, 4 wk
Jia HL (2015) [23]	30 (16/14)	30 (13/17)	30.6 mo	31.2 mo	Catgut	2 cm, No. 2/ NR, NR	* KI17, ST24, CV6, ST36, SP6 † BL12, BL17, BL18, BL23	Digital acupoint pressure	1/15 d, 2, 30 d	AT	* EX-B2, GV14, BL10, SI3 † BL12, BL17, BL18, BL23	3/1 wk, 12, 4 wk
Chen CY (2016) [32]	80 (45/35)	80 (47/33)	6.51 mo	6.19 mo	Catgut	1 cm, NR/ NR, NR	* EX-B2(both) † None	HM	1/10 d, 2, 22 d	AT	* EX-B2 (both) † LI4, LI11, LI14	1/1 d, 20, 22 d
Yang L (2016) [25]	36 (NR/NR)	36 (NR/ NR)	NR	NR	PDO	1-2 cm, No. 4-0/ NR, NR	* EX-B2, BL12 † GV20, GB20, LI4, LI11, BL15, GV14	-	1/1 wk, 2, 2 wk	AT	* EX-B2, BL12 † GV20, GB20, LI4, LI11, BL15, GV14	1/1 d, 14, 2 wk
Wang M (2016) [20]	40 (25/15)	40 (24/16)	2.72 y	2.82 y	PDO	1-2 cm, No. 4-0/ 4 cm, 0.3 mm	* EX-B2 (affected level, both), BL11, BL12 † GV20, GB20, LI11, LI4, BL13, GV14, BL15	-	1/1 wk, 2, 2 wk	AT	* EX-B2 (affected level, both), BL11, BL12 † GV20, GB20, LI11, LI4, BL13, GV14, BL15	1/1 d, 14, 2 wk
Yang Y (2021) [24]	50 (26/24)	50 (24/26)	1.2 y	1.2 y	Catgut	2 cm, NR/ NR, 0.9 mm	* Inferior border of the SP of affected level and side of nerve root, 2 cm outside the centerline. BL18, BL23 (affected side) † None	NB	TEA 1/2 wk, 2, 4 wk NB 1/1 wk, 4, 4 wk	AT	* EX-B2, GV14, BL10, SI3 † None	1/1 d (6 d/ wk), 24, 4 wk

Table 1. (continued).

Study ID (author [y])	Sample size [enrolled→analyzed (male/female)]		Duration of CR (mean)		Treatment details of experimental group					Treatment details of control group		
	EG	CG	EG	CG	Materials	Thread size (length, USP)/ needle size (length and diameter)	TEA points	Concomitant treatment	Frequency, sessions, duration of treatment	Type of control	Treatment points	Frequency, sessions, duration of treatment
Ding M (2012) [22]	58 (39/19)	62 (41/21)	30.65 mo	29.03 mo	PDO	1-2 cm, No. 4-0/ NR, NR	* EX-B2(affected level, both), BL11, BL12 † GB20, GV20, LI11, LI4, GV14, BL13, BL15	-	1/1 wk, 2, 2 wk	AT	* EX-B2 (affected level, both), BL11, BL12 † GB20, GV20, LI11, LI4, GV14, BL13, BL15	1/1 d, 14, 2 wk
Sun NN (2019) [16]	45 (28/17)	45 (25/20)	2.36 y	2.40 y	Catgut	NR, NR/ NR, NR	* EX-B2 † None	HM	TEA 1/10 d, 2, 22 d HM 3/1 d, 60, 22 d	AT	* EX-B2 (both) † LI4, LI11, LI14	1/1 d, 20, 22 d
Comparison with other remedies												
Cheng SZ (2018) [31]	73 (34/39)	73 (28/45)	2.49 y	2.57 y	NR	2 cm, No. 2-0/ NR, 0.8 mm	* EX-B2 (C-spine, T7), Wuxing & Bagua point at umbilical region (Qian Gua, KanGua, Zhen Gua, Li Gua), tender points at shoulder and back, especially infraspinatus and teres minor † None	-	1/15 d, 3, 45 d	AT + EA	* EX-B2, GV14, GB20, GB21, LI15, TE3, SI3 (EA at GV14, GB21) † None	1/1 d, 30, 31 d
Xue QL (2010) [17]	AP + TEA 70 (38/32)	AP 70 (39/31)	AP + TEA 2.8 y	AP 3.1 y	Catgut	2 cm, No. 0/ NR, 0.9 mm	* The point where the parallel line passing through the SP of affected level meets the BL 1st line of the cervical spine, tender points at neck, shoulder and back, GV14, SI3, TE5 † None (AP followed by TEA)	AP (same points with CG)	1/10 d, 3, 30 d	AP	* Superior & inferior border of the SP of affected level (interspinal ligament), The point where the parallel line passing through the SP of affected level meets the BL 1st line of the cervical spine, tender points at neck, shoulder and back † None	1/10 d, 3, 30 d
	TEA 70 (41/29)		TEA 3.0 y		Catgut	2 cm, No.0/ NR, 0.9 mm	* EX-B2, GV14, SI3, TE5 † None	-	1/10 d, 3, 30 d			

Table 1. (continued).

Study ID (author [y])	Sample size [enrolled→analyzed (male/female)]		Duration of CR (mean)		Treatment details of experimental group					Treatment details of control group		
	EG	CG	EG	CG	Materials	Thread size (length, USP)/ needle size (length and diameter)	TEA points	Concomitant treatment	Frequency, sessions, duration of treatment	Type of control	Treatment points	Frequency, sessions, duration of treatment
Zhang Z (2021) [29]	35 (19/16)	35 (17/18)	2.83 mo	2.94 mo	PGLA	0.5–1 cm, No. 4/ 6.9 cm, 0.7 mm	* EX-B2 (C4-6), GV14, BL11 † None	RG+NB (same points with CG)	1/2 wk, 2, 4 wk	RG + NB	* The midpoint between lateral mass and centerline of the affected level	1/2 wk, 2, 4 wk
Wang HY (2015) [28]	60 (NR/NR)	60 (NR/ NR)	NR	NR	Catgut	1 cm, NR/ NR, NR	* EX-B2 † None	Western medical symptomatic treatment (cervical thermotherapy, neurotrophic therapy, TR etc.) + HM	NR, NR, 2 wk (1 y f/u)	Western medical symptomatic treatment (cervical thermotherapy, neurotrophic therapy, TR etc.)	NR	NR, NR, 2 wk (1 y f/u)
Huang Z (2018) [30]	50→48 (12/36)	50 (15/35)	46.27 mo	45.18 mo	Collagen	0.5 cm, No .4–0/ NR, NR	* Jingxue point, Shangzhixue point (right and left alternation) † None	AT + MX (same points with CG)	AT + MX 1/2 d, 12, 24 d TEA 1/1 wk, 4, 4 wk (TEA starts after completing AT + MX)	AT + MX (0.25 mm × 40 mm)	* EX-B2 (affected level), GV14, Ashi points, TE5, LI4 † GV16 BL12, BL17, SP10, SP9, ST40, BL18 BL23, ST36 CV6, GV20 GB20, GB21, LI11, LI10 (warm needling at EX-B2 [affected level], GV14, Ashi point)	1/2 d, 12, 24 d

* Fixed points.
† Individualized points.
AP, acuputomy; AT, acupuncture treatment; CG, control group; DAPE, deep-layer acupoint PGLA embedding group; EA, electroacupuncture; EG, experimental group; HM, herbal medicine; MAPE, middle-layer acupoint PGLA embedding group; MX, moxibustion; NB, nerve blocks; NR, not recorded; PDO, polydioxanone; PGLA, polyglycolide-lactide; RG, radiculography; SAPE, shallow-layer acupoint PGLA embedding group; SHAE, sham acupoint embedding group; SP, spinous process; TEA, thread embedding acupuncture; TR, traction; US, ultrasound guide; USP, United States Pharmacopoeia monographs.

Table 2. Results and Adverse Events of the Included Studies.

Study ID (author [y])	Outcome measures	Results*	Safety Profile [group : *n* (%), adverse event (*n*)]
		Comparison with sham TEA	
Chu YX (2018) [14]	1) VAS, 2) NDI, 3) YT-20, 4) SF-36 (4-1) PCS, (4-2) MCS)	1) DAPE†, MAPE†, SHAE‡; DAPE > SHAE§, MAPE > SHAE§, DAPE > MAPE§ 2) DAPE†, MAPE†, SHAE‡; DAPE > SHAE§, MAPE > SHAE§, DAPE = MAPE (3 wk)‖, DAPE > MAPE (4 wk)§ 3) DAPE†, MAPE†, SHAE‡; DAPE > SHAE (3 wk)§, DAPE = SHAE (10 wk)‖, MAPE > SHAE§, DAPE = MAPE‖ 4-1) DAPE (3 wk)†, DAPE (10 wk)†, MAPE†, SHAE‡; DAPE > SHAE§, MAPE > SHAE§, DAPE > MAPE§ 4-2) DAPE (3 wk)†, DAPE (10 wk)†, MAPE†, SHAE‡; DAPE > SHAE§, MAPE > SHAE§, DAPE = MAPE‖	DAPE: 1 (0.03%) tingling (1) MAPE: 2 (0.06%) tingling (2) No specific mention, but not serious AEs: 2¶
		Comparison of different TEA depths	
Sun WS (2015) [33]	1) VAS, 2) NDI, 3) YT-20, 4) PRI, 5) PPI	1) 4) 5) SAPE (NR), MAPE†, DAPE†; MAPE > SAPE§, DAPE > SAPE§ 2) SAPE (NR), MAPE†. DAPE†; DAPE > MAPE§, DAPE > SAPE§, MAPE > SAPE§ 3) SAPE‡, MAPE‡, DAPE†; DAPE > SAPE§, DAPE > MAPE§	NR
		Comparison of different TEA materials	
Feng H (2012) [21]	1) VAS, 2) NDI	1) 2) PDO†, Catgut†, AT†; PDO > AT§, Catgut > AT§, PDO = Catgut‖	NR
	1) adverse reaction rate (1-1) pain, 1-2) redness, 1-3) induration)	1-1) 1-2) 1-3) PDO = Catgut (right after the treatment)‖, Catgut > PDO (1 wk)§ 1-1) 1-2) 1-3) Catgut < PDO (2 wk)§	NR
		Comparison of different TEA insertion methods	
Sun WS (2018) [34]	1) VAS, 2) NDI, 3) YT-20, 4) PRI, 5) PPI	1) 2) 4) 5) EG†, CG†; EG > CG§ 3) EG > CG§	EG: none CG: 3 (10%) partial edema (2), dizziness & nausea (1)
Yang CD (2012) [19]	1) ER (1-1) FR)	1) EG = CG‖ 1-1) EG > CG§	NR
		Comparison with acupuncture	
Sun WS (2013) [15]	1) ER, 2) VAS, 3) YT-20, 4) PRI, 5) PPI	1) EG > CG§ 2)4) 5) EG†; EG > CG§ (4) CG† 3) EG†, CG†; EG > CG§	NR
Qiu C (2015) [35]	1) ER	1) EG > CG§	NR
Li RQ (2015) [26]	1) ER, 2) VAS, 3) YT-20, 4) PRI, 5) PPI	1) EG > CG§ 2) 4) 5) EG > CG§, EG†2) 4) CG†, 5) CG‡) 3) EG†, CG†; EG > CG§	NR
Jia HL (2015) [23]	1) ER 2) analgesic effective rate	1) 2) EG > CG§	NR
Chen CY (2016) [32]	1) ER, 2) VAS, 3) cervical ROM (flexion, extension, side bending, rotation)	1) EG > CG§ 2) EG†, CG†; EG > CG§ 3) EG†, CG†; EG > CG§	NR
Yang L (2016) [25]	1) ER, 2) VAS, 3) NDI	1) EG > CG§ 2) 3) EG†, CG†; EG > CG§	NR
Wang M (2016) [20]	1) ER, 2) VAS, 3) NDI	1) 2) 3) EG > CG§	NR
Yang Y (2021) [24]	1) ER, 2) VAS, 3) YT-20, 4) cervical ROM score	1) EG > CG§ 2) 3) EG†, CG†; EG > CG§ 4) EG†, CG†; EG > CG§	NR
Zhao WX (2019) [27]	1) ER, 2) VAS, 3) adverse reaction rate	1) EG > CG§ 2) EG†, CG†; EG > CG§ 3) none, EG = CG‖	EG: none CG: none
Ding M (2012) [22]	1) ER, 2) VAS, 3) NDI	1) EG > CG§ 2) 3) EG†, CG†; EG > CG§	NR

Table 2. (continued).

Study ID (author [y])	Outcome measures	Results*	Safety Profile [group : *n* (%), adverse event (*n*)]
Sun NN (2019) [16]	1) ER, 2) VAS, 3) NPQ (neck pain scale)	1) EG > CG§ 2) 3) EG > CG§	NR
		Comparison with other remedies	
Cheng SZ (2018) [31]	1) ER, 2) VAS, 3) symptom score, 4) adverse reaction	1) 3) EG > CG§ 2) NR 4) None	EG: none CG: none
Xue QL (2010) [17]	1) ER (1-1) FR)	1) 1-1) AP+TEA > TEA (NR of p), AP+TEA > AP (NR of p) 1) TEA = AP‖	NR NR
Feng YT (2021) [18]	1) ER (1-1) FR), 2) VAS	1) 1-1) EG > CG§ 2) EG = CG (6hr)‖, EG = CG(3d)‖, EG > CG (1 wk)§, EG > CG (1 mo)§	NR
Zhang Z (2021) [29]	1) ER, 2) VAS, 3) NDI	1) EG > CG§ 2) 3) EG (1 wk)†, EG (4 wk)†, CG (1 wk)†, CG (4 wk)†; EG > CG (1 wk)§, EG > CG (4 wk)§	EG: 3 (8.57%) gastritis (1), blood sugar rise (2) CG: 4 (11.43%) gastritis (1), blood sugar rise (3)
Wang HY (2015) [28]	1) ER, 2) recurrence rate	1) 2) EG > CG§	NR
Huang Z (2018) [30]	1) ER, 2) NDI, 3) YT-20	1) EG > CG§ 2) 3) EG†, CG†; EG > CG§	NR

* Regardless of the actual value of the evaluation index, the therapeutic effect in the groups is marked with > or =.
† Significant difference compared with before treatment, $p < 0.05$.
‡ Not statistically different compared with before treatment, $p > 0.05$.
§ Significant differences between groups after treatment, $p < 0.05$.
‖ There was no significant difference between groups after treatment, $p > 0.05$.
¶ No comment about which group the adverse event occurred in.
CG, control group; DAPE, deep-layer acupoint PGLA embedding group; EG, experimental group; ER, total efficacy rate; FR, full recovery rate; HSV, high shear viscosity; LSV, low cut viscosity of whole blood; MAPE, middle-layer acupoint PGLA embedding group; MCS, mental component summary; NDI, Neck Disability Index; NPQ, Northwick Park Neck Pain Questionnaire; NR, not recorded; PCS, physical component summary; PDO, polydioxanone; PGLA, polyglycolide-lactide; PPI, Present Pain Index; PRI, Pain Rating Index; PV, plasma viscosity; ROM, range of motion; SAPE, shallow-layer acupoint PGLA embedding group; SF-36, Short Form 36-Item Health Survey; SHAE, sham acupoint embedding group; TEA, thread embedding acupuncture; VAS, Visual Analogue Scale; YT-20, Yasuhisa Tanaka 20.

Experimental intervention

All the studies included in this review used TEA as an experimental intervention. Five studies used TEA in both treatment and control groups [14,19,21,33,34]. Two compared TEA depths [14,33] and one compared different TEA materials [21]. The other two studies compared different TEA insertion methods [19,34], including an accompanying ultrasound guide [34] and different types of embedding needles [19].

Concomitant treatment

Herbal medicine [16,28,32], was the most commonly used concomitant treatment with TEA. Cervical traction [19,28], nerve blocks [24,29] and acupotomy (AP) [17,18] were also used. Cervical thermotherapy, neurotrophic therapy [28], digital acupoint pressure [23], and acupuncture and moxibustion treatment [30] were also used with TEA.

Control intervention

Acupuncture treatment alone was the most common control intervention in 12 studies [15,16,20-27,32,35], but 1 used electroacupuncture (EA) [31] and 1 used both acupuncture and moxibustion treatment [30]. Nerve blocks [29], AP [17,18], Western medicine symptomatic treatment including cervical thermotherapy, neurotrophic therapy, and cervical traction [28] and sham TEA [14] were also applied as control interventions.

Therapeutic effects

Comparison with sham TEA

One study by Chu et al [14] compared sham TEA with real TEA. Real TEA patients were assigned into a middle-layer acupoint PGLA embedding (MAPE) group and a deep-layer acupoint PGLA embedding (DAPE) group. Sham TEA involves threadless insertion at the same acupoint and depth as DAPE under ultrasound guidance. Sham TEA showed no significant change before and after treatment according to any of the evaluation indicators ($p > 0.05$). For all evaluation indicators, DAPE, and MAPE showed significant improvement compared with sham TEA after treatment.

Comparison of different TEA depths

Two studies performed TEA at different depths. Sun et al [33] assigned patients into shallow, middle, and deep layer TEA, and Chu et al [14] assigned patients into middle and deep layer TEA combined with ultrasound guidance. The shallow layer group had threads planted subcutaneously, the middle layer group had threads planted in the semispinalis capitis, and the deep layer group had threads planted in the multifidus. Based on all result indicators (VAS, NDI, YT-20, Pain Rating Index, and Present Pain Index), TEA was more effective in the DAPE group compared with the shallow-layer acupoint PGLA embedding (SAPE) group. MAPE was more effective than SAPE according to all indicators except YT-20. A comparison of DAPE with MAPE showed that DAPE had significantly better or similar therapeutic effects to MAPE.

Comparison of different TEA materials

One study [21] compared different materials, assigned patients into three groups to perform acupuncture, TEA with PDO and catgut, respectively. When comparing the VAS and NDI, both the PDO and catgut groups showed significantly better results after treatment than before treatment. There was no significant difference between the PDO and catgut groups after treatment.

Comparison of different TEA insertion methods

Two studies used the same TEA materials and acupoints across all groups, with the only difference being the insertion method. Sun et al [34] compared the effect of ultrasound-guided TEA and the conventional method of thread implantation. The therapeutic effect was better under ultrasound guidance than the conventional method for all outcome indicators. Yang et al [19] used different embedding needles. A newly designed flat blade needle was used for the treatment group and it was expected to have similar effects to AP, and a conventional embedding needle was used for the control group. There was no difference between the two groups regarding the total efficacy rate, but the full recovery rate was significantly higher when a flat blade needle was used.

Comparison with acupuncture

Twelve studies compared TEA with acupuncture alone [15,16,20-27,32,35]. Of these, eight studies [15,20-22,25-27,35] compared only TEA and acupuncture without other concomitant treatments in the treatment group. For the remaining four studies, the treatment group was treated with herbal medicine [16,32], digital acupoint pressure [23], or nerve blocks [24] as well as TEA. Based on all outcome indicators, the TEA treatment group showed more improvement than the acupuncture group.

Comparison with other remedies

Six studies compared TEA with other treatments. Compared to EA, TEA was significantly superior in terms of the total efficacy rate and the symptom score [31]. Two studies compared TEA with AP. Xue et al [17] assigned patients into three groups: single AP, single TEA, and TEA combined with AP. The combined group had higher total efficacy and full recovery rates than either the single AP or single TEA group. The single TEA and single AP groups displayed no significant difference in the total efficacy rate ($p > 0.05$). Feng et al [18] also showed that the combined group had significantly higher total efficacy and full recovery rates compared with the group that received AP alone.

Zhang et al [29] performed radiculography and nerve blocks for a control group. Wang et al [28] administered Western medical symptomatic treatment including cervical thermotherapy, neurotrophic therapy, cervical traction, and Huang et al [30] performed combination therapy with acupuncture and moxibustion. In these three studies, intervention in the treatment group involved adding TEA to the comparison control group. In all three studies, the treatment group showed significantly better effects than the control group ($p < 0.05$).

Safety

Feng et al [21] evaluated the safety of TEA materials by measuring the adverse reaction rate. Catgut was inserted into the right and PDO was inserted into the left EX-B2 in 100 patients without dividing the group. In this study, adverse reactions were categorized as pain, redness, and incidence of induration. The adverse reaction rate between PDO and catgut showed no difference immediately after treatment. However, PDO had a significantly lower adverse reaction rate compared with catgut after 1 and 2 weeks for all indicated side effects.

Among 22 RCTs, 3 studies mentioned the presence of AEs from TEA [14,29,34], and 2 studies reported no side effects [27,31]. The remaining studies provided no indication of side effects during the research.

Chu et al [14] compared the safety of thread insertion depths. In MAPE and DAPE, tingling sensations occurred in three patients after inserting the thread into the neck, but the side effects required no medical management, and all patients fully recovered from the side effects. The two AEs in this study were not specifically described, but the authors stated that they were non-serious. Sun et al [34] compared the ultrasound-guided method with the conventional method of TEA insertion. The ultrasound-guided treatment group had no AEs, but the control group that received conventional TEA experienced partial edema, dizziness, and nausea. Zhang et al [29] used radiculography and nerve blocks as controls, and added TEA to the treatment group. Gastritis and a rise in blood sugar occurred in both the treatment and control groups, with no significant differences.

When analyzing only the 5 RCTs that reported AEs, 6 of the 281 patients (2%) who received TEA had mild to moderate side effects. No serious AEs were reported.

Quality assessment

The ROB 2 tool was used to conduct a quality assessment (Figs. 2 and 3). From the random sequence generation, nine studies that applied random number tables and one study that used a computer [14] were deemed at "low risk" of bias. One study stated in the abstract that the researchers randomly divided patients according to the order of their visits, but the full text did not include the word "random" and was therefore assessed as "high risk" [29]. The other 11 studies did not mention a specific method of random assignment

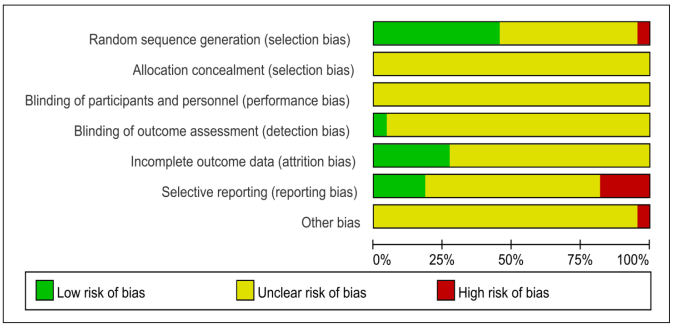

Fig. 2. Risk of bias in the included studies.

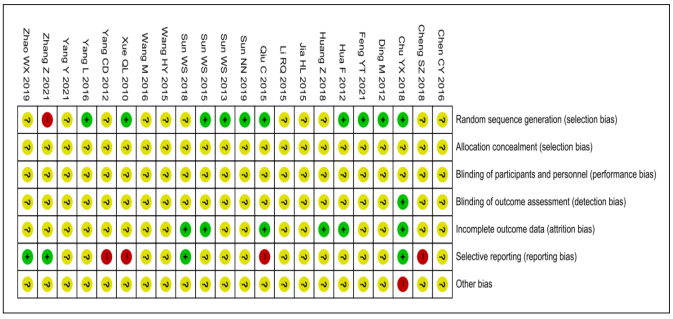

Fig. 3. Risk-of-bias summary.

and were judged as "unclear risk" of bias.

Only one study mentioned allocation concealment and that an experienced statistician produced a computer-generated randomization schedule, but it was not clear whether the statistician was a third party or not, therefore, this study was judged as a "unclear risk" of bias [14]. The remaining studies did not mention blind methods, so they were all classified as "unclear risk".

Performance bias was stated in only one study [14], which used sham TEA to blind the participants, but due to the nature of the intervention, the operator was not blinded. This study was judged an "unclear risk" of bias. The remaining studies did not mention blinding, so they were all deemed "unclear risk" of performance bias.

Regarding detection bias, only one study [14] mentioned blinding outcome assessors, data collectors, and statisticians, so it was classified as "low risk." All the other research was evaluated as "unclear risk" of detection bias since there was no mention of a separate evaluator.

Regarding attrition bias, one study [14] included dropouts in the results, four studies [20,24,33,35] suggested elimination criteria, although there was no mention of dropouts, and two studies had low proportions of dropouts (6% [21] and 2% [30]), so they were classified as "low risk." All the remaining studies were judged as "unclear risk" of attrition bias since there was no mention of dropouts.

Regarding reporting bias, four studies were deemed "low risk" because there were no missing values [14,27,29,34]. Of the four "high risk" studies, three described and measured only the total efficacy or full recovery rates as outcome indicators [17,19,35], and one study stated that VAS score was measured as an outcome indicator, but the results were not reported [31]. The remaining 14 studies were categorized as "unclear risk" of reporting bias since they provided no information about AEs [15,16,18,20-26,28,30-32].

Regarding other types of bias, one study [14] allowed patients to take pain medication when needed, but did not mention whether they took it or not. Since this study relied on subjective outcome measures, it was judged as "high risk" because it did not rule out the possibility that pain decreased due to painkillers. In six studies [17,18,20,25,27,31], the explanation or source of the "efficacy rate" or "symptom score" they set as the result index was unclear. Eight studies did not clearly show significant differences in outcome indicators between pretreatment groups [18,20-22,24,30-32] and were therefore classified as "unclear risk" of other bias.

Discussion

This study analyzed 22 RCTs (2,483 patients) that reported the efficacy and safety of TEA for CR. Studies were selected from 16 domestic and international databases, to August 22, 2022. Recently, one review on TEA for CR was published [11] and concluded that TEA had a better therapeutic effect than acupuncture or EA, but had more AEs (subcutaneous congestion) than acupuncture. However, the quality and number of RCTs reviewed were low. This review examined a larger number of studies and conducted various analyses.

Considering the basic features of TEA used in the studies (in China), catgut was (and continues to be) the most widely and consistently used material. However, according to Feng et al [21], catgut caused a higher incidence of pain, redness, and induration than PDO. Huang et al [36] observed that severe AEs, such as necrosis, skin ulcers, and suppuration, occurred mostly with the use of catgut or chromic catgut. Changing the materials used in TEA in China may be advisable. In Korea, catgut has been reported to be less safe than PDO or PGLA, so it is rarely used, and most clinicians use PDO [37].

Regarding the size of TEA tools, the thread lengths used were short (0.5-3 cm), with an average length of 1.3 cm. Thread diameters were thick, ranging from USP 4-0 to 2, and the most frequently used diameter was USP 2-0 (i.e., 0.3-0.339 mm) [9]. The embedding needles were thick. No. 9 needles (0.9 mm diameter) were used most often, but the needle length was rarely reported. In China, the thickness of the embedding needle is usually marked with a standard number; therefore, Chinese studies rarely specify a diameter. Jun et al [38] mentioned that in China, the No. 6 needle was a diameter of 0.6 mm, and No. 7 needle was a diameter of 0.7 mm. Based on this, the diameter of the needle was analyzed. However, in Korea, the threads used are mostly 2.5-9 cm long and 0.069-0.149 mm thick (USP 7-0 to 5-0), with 25G (diameter 0.5 mm) to 30G (diameter 0.26 mm) needles [9]. Therefore, the studies included in this review, which were conducted in China, used thicker and shorter threads with thicker needles than is typical in Korea. The TEA tools seem to differ from typical Korean tools due to the specificity of the insertion method. In China, when

embedded into acupoints, the medical threads are cut short and inserted with tools, such as plungers [38]. Therefore, the findings determined from this review seem difficult to apply it to the situation of domestic research in Korea.

The main treatment sites for CR were local acupoints, especially EX-B2 and GV14. Two studies [23,30] administered treatment using distal acupoint properties without local acupoints. When distal acupoints alone were treated, the treatment had a more significant effect than the control group, which used local points. It would be interesting for more studies to use distal acupoints in the future.

The usual frequency of TEA was once every 7-15 days, and once a week was the most common. The total treatment period for TEA ranged from 2-6 weeks, and 28-30 days was the most common.

Regarding concomitant treatment, many of the studies combined herbal medicine, cervical traction, nerve blocks, and AP with TEA. This is worth examining further in TEA-related RCTs or in clinical practice. Generally, acupuncture is the easiest cotreatment with TEA for treating CR. However, among the studies on TEA for CR, no research has compared acupuncture alone with acupuncture combined with TEA. Therefore, more research is necessary.

The most frequently used outcome measure in this review was the total efficacy rate. This rate is mainly based on Chinese medical diagnostic evaluation and is divided into "full recovery," "significant effect," "moderate effect," and "no effect." Based on this, the total efficacy rate indicates ratios higher than a "moderate effect." The "full recovery" rate can also be measured. This reflects the subjectivity of the evaluator or the patient and involves only three or four evaluations. Therefore, the reliability or discrimination power of total efficacy rate can be lower than indicators evaluated by a score, such as the VAS or NDI [11]. In addition, each study described the definitions and efficacy evaluation criteria slightly differently, reducing the objectivity of the studies. Therefore, there is a need to standardize the efficacy evaluation criteria for CR and cervical condition/disease. The 2nd most frequently used outcome measures were the NDI and VAS. These are considered objective, detailed, and simple but user-friendly numerical scales. Therefore, scales like these should be used in future studies.

Various studies have compared the therapeutic effects of TEA. Sham TEA, with only the thread missing from real TEA, was an ineffective treatment compared with real TEA, where it was possible to compare the effects of the thread. Since sham TEA resembles acupuncture in that only the needle is inserted and removed, this is consistent with the results that TEA was more effective than acupuncture [15,20-22,25-27,35]. Comparing the depth of needle insertion used for TEA, the depths were divided into shallow layer (subcutaneous), middle layer (semispinalis capitis), and deep layer (multifidus), the deeper the TEA, the better the treatment effect was in most of the cases [14,33].

When comparing TEA materials, catgut and PDO showed no observed difference in the effectiveness of treatment, however, catgut was less safe [21].

Regarding TEA implementation methods, ultrasound guidance had significantly fewer side effects and better therapeutic effects compared with the conventional method [34]. It seems that the use of an ultrasound guidance targets the intended structure and depth of cervical muscles more accurately. However, a more specific description of the method, such as the angle of entry, and in-plane, out-plane would be valuable.

The use of a flat blade needle as an embedding needle, which resembles AP, was significantly better than the use of a conventional embedding needle [19]. TEA tools like this would be useful for domestic introduction in Korea. It is also necessary to develop various types of TEA.

Single TEA was better than single acupuncture [15,20-22,25-27,35], and the results were consistent with the conclusion of a previous review on TEA for CR [11]. However, many studies have applied similar designs and acupoints, so more diverse approaches are needed.

When compared with other remedies, TEA was also better than EA [31]. TEA combined with AP was better than single AP or single TEA. There was no significant difference between single AP and single TEA [17,18]. In some studies, concomitant treatment that was not used in the control group was performed alongside TEA in the treatment group [16,23,24,28,32]. In these cases, although the studies concluded that the experimental groups showed improvement, it is difficult to determine whether the therapeutic effect was due to concomitant treatment or TEA.

Regarding safety, five studies [14,27,29,31,34] reported side effects; only 2% (6 out of 281 patients) who received TEA had mild to moderate side effects, and no serious AEs were reported. Although many studies did not indicate AEs, considering that 281 people in 5 RCTs is a considerable number, it seems that TEA is relatively safe. However, future TEA studies conducted on CR patients should report the AEs of treatment.

Regarding the risk of bias, only half of the 22 studies described specific random allocation methods. Concerning allocation concealment, blinding of participants, and outcome assessment, no studies made any mention of them, except one study [14]. Trials with inadequate or unclear allocation concealment can produce up to 40% larger estimates of treatment effects [39]. In the case of performance bias, concealment may be difficult due to the nature of the treatment, but researchers should attempt to minimize selection and detection bias to improve the quality of research. Only four studies mentioned dropouts [14,21,27,30], only five studies mentioned AEs [14,27,29,31,34], and the remainder gave no indications. In addition, a few studies did not compare VAS scores as expected [31], did not report the significance of the results [17], or made no mention of the frequency and number of treatments [18]. Overall, many details were omitted, making it difficult to judge the risk of bias.

This review has several limitations. Due to differences between the acupoints, methods, and manipulations of TEA, there may be considerable heterogeneity in this study's results. Most of the RCTs in this review were published in China using Chinese; hence, language bias may have been introduced due to the problem of language interpretation. Although the number of studies included in this review was limited, TEA seems to be an effective treatment for CR. However, more research is needed to draw definite conclusions. RCTs should be conducted and carried out in strict compliance with the Consolidated Standards of Reporting Trials (CONSORT) Statement [40] and standardized reporting.

The selection and reporting of appropriate patients, populations, interventions, comparisons, and outcomes (PICO) should be based on PICO standards [41]. High-quality RCTs with a low risk of bias on TEA treatment of CR should be conducted.

Conclusion

Based on 22 studies that considered TEA treatment for CR, TEA appeared to be a safe treatment and may effectively relieve pain in CR patients. However, there were some limitations to this review due to unreported or omitted data, language, concomitant treatments, and the heterogeneity of the included studies.

Author Contributions

Conceptualization: HES and KJS. Methodology: HES. Formal investigation: HES, LHJ and LJH. Data analysis: HES, LHJ, LJH, KJS, WSH and CSH. Writing original draft: HES. Writing – review and editing: HES, LHJ, LJH, LYK and KJS.

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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