J Acupunct Res 2022;39(3):159-169

Journal of Acupuncture Research

Journal homepage: http://www.e-jar.org

Review Article

Effectiveness of Electroacupuncture for Patients with Failed Back Surgery Syndrome: A Systematic Review and Meta-analysis

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Article history:
Submitted: March 28, 2022
Revised: June 02, 2022
Accepted: June 23, 2022

Keywords:
electroacupuncture, failed back surgery syndrome, meta-analysis, systematic review

https://doi.org/10.13045/jar.2022.00115
pISSN 2586-288X eISSN 2586-2898

ABSTRACT

Failed back surgery syndrome (FBSS) is a term that applies to symptoms such as persistent or recurring low back pain, paresthesia, sciatica, or numbness after spine surgery. Electroacupuncture (EA) has been reported to have excellent analgesic effects although there have been no systematic reviews on the effects of EA on FBSS. Therefore, a systematic review and meta-analysis of the effectiveness of EA on FBSS was conducted. Eight databases were searched for studies that used EA for FBSS and 7 randomized controlled trials (RCTs) were included. RCTs of EA as combination therapy for FBSS compared with conventional treatment demonstrated improvement in the level of pain, lumbar functional scale scores, and quality of life. However, meta-analysis showed that reduction in pain was not statistically significant, while evaluation of lumbar function significantly improved, although the quality of evidence in the RCTs was generally low. RCTs comparing EA alone with conventional treatment demonstrated an improved level of pain, lumbar function, and effective rate of treatment. Meta-analysis showed that pain was significantly decreased in the EA alone group compared with the control group, although the quality of evidence was low. To improve the quality of evidence, high-quality RCTs are required in the future.

Introduction

Low back pain (LBP) is one of the most common reasons for visiting hospital in the United States, with 15-20% of adults experiencing LBP during a single year [1]. Following the Mixter and Barr study which reported that intervertebral disc herniation is a cause of LBP and sciatica, spine surgery for the treatment of LBP has become prevalent [2]. Consequently, over the 10 years between 1998 and 2008, the number of lumbar fusion surgeries in the United States increased from 77,682 to 210,407 and the cost of surgeries exceeded 16 billion [3].

Although surgery is performed to manage the potential cause of LBP, 10-40% patients still have persistent back pain or sciatica after surgery [4]. A follow-up study performed for more than 10 years showed that 74.6% of patients had residual LBP after surgery. Moreover, 12.7% of patients had severe LBP that required reoperation [5]. The International Association for the Study of Pain (IASP) defined this situation as failed back surgery syndrome (FBSS), described as "lumbar pain of unknown origin that persists despite surgical intervention or appears after surgical intervention for spinal pain originally in the same topographical distribution" [6]. The term FBSS was first introduced by North et al to describe persistent or recurrent pain after one or more lumbar surgeries [7]. A more functional definition has been proposed whereby FBSS is

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the mismatch between the outcome (of the lumbar spine surgery) and the expectation (of patient and surgeon) [4]. The term FBSS is ambiguous and cannot be reliably used to describe the diversity of clinical information. There is a proposal to replace FBSS with chronic pain after spinal surgery (CPSS) or persistent spinal pain syndrome [8,9]. In 2019, the IASP recommended the replacement of FBSS with CPSS [10]. However, in this review, the term FBSS was used because of the wide historic use of the term FBSS by clinicians.

A previous study in the UK showed that 87% of the patients with FBSS had received more than four types of pharmaceutical drugs (antidepressants, anticonvulsants, or pain-relieving nerve injections) or non-drug treatments (physical rehabilitation, transcutaneous electrical nerve stimulation, acupuncture, or psychological interventions), and 78% of the patients could not return to work [11]. Despite the development of surgical skills, the success rate of the 2nd surgery was approximately 30%, which reduced to 15% for the 3rd surgery, and 5% for the 4th [11]. Therefore, nonsurgical treatment is recommended rather than reoperation [12]. For nonsurgical treatments, nonsteroidal anti-inflammatory drugs are the first choice, although when symptoms worsen, the use of a narcotic agent is considered. The recent widespread use of opioids have been reported to be associated with narcotic addition in patients with FBSS and this has become a serious social problem [13].

Acupuncture is a relatively safe and effective technique to treat FBSS with fewer side effects [14]. Electroacupuncture (EA) is a form of acupuncture where electrical stimulation is applied between 2 acupuncture needles inserted into a meridian point or acupoint. It has been reported that that EA has a quicker and stronger analgesic effect than manual acupuncture (MA) [15]. Therefore, EA could be a more effective intervention method for FBSS than MA. A systematic review of the effectiveness of MA for acute postoperative pain after back surgery has been published previously [16]. However, there has been no systematic review of randomized controlled trials (RCTs) on the effectiveness of EA in patients with FBSS. Therefore, a systematic review and meta-analysis to identify whether EA is effective for patients with FBSS was performed.

Materials and Methods

Study design

This study was a systematic review and meta-analysis of the effectiveness of EA in patients who developed pain after spine surgery due to FBSS. This study was conducted in compliance with the guidelines of Preferred Reporting Items for Systematic reviews and Meta-Analysis 2020. The study protocol was registered on The International Prospective Register of Systematic Reviews (PROSPERO; registration no.: CRD42022319531) [17].

Eligibility criteria

Types of included studies

In this study, only RCTs were included for analysis. Non-RCTs, such as review articles, qualitative research, and protocols, were excluded. In addition, non-human research and studies in which full-text articles could not be identified were also excluded.

Types of participants

This study included patients who met the IASP definition for FBSS, that is, those with LBP of unknown origin, which either persisted despite surgical intervention or reappeared after surgical intervention for spinal pain originally in the same topographical distribution. Patients who had persistent lower limb pain or numbness with LBP after surgery, were also included. No limitation was applied on the type of surgery or duration before onset of symptoms following surgery, and patients were included in the study regardless of their race, age, and sex. However, patients who developed LBP due to surgery were excluded.

Types of interventions

The treatment methods of the intervention group included EA, and therapeutic methods that combined electrical stimulation, with acupuncture were also included [18]. All studies that used EA as a monotherapy or combination therapy with other treatments were included. There were no limitations on the type of needle used for EA.

Types of outcome measure

Scales measuring pain, such as the visual analog scale (VAS) and numerical rating scale, were used as a measure of the primary outcome. The Oswestry Disability Index (ODI) measuring the functional scale of the lumbar spine, the Japanese Orthopedic Association (JOA) score which evaluates neurological and functional status, the EuroQol-5 dimensions (EQ-5D) which is an instrument that assesses quality of life, and the total effective rate (TER) of intervention were considered as a measure of secondary outcomes. In addition, adverse events (AEs) were included as secondary outcomes.

Data source and search strategy

There were 2 English language databases [MEDLINE (via PubMed) and Cochrane Register of Controlled Trials (CENTRAL)], a Chinese database [China Knowledge Infrastructure for Chinese studies (CNKI)], a Japanese database [Japan Science and Technology Information Aggregator Electronic database (J-STAGE)], and 4 Korean databases (Korea Medical Database, Oriental Medicine Advanced Searching Integrated System, Korean Studies Information Service System, and Research Information Sharing Service) searched to retrieve studies published up to February 2022. Search strategies within PubMed for lumbar surgery, interventions, and surgical methods are shown in Table 1. For databases in other languages similar search strategies were applied.

Study selection and data collection process

Two researchers independently performed the literature search and selection in accordance with the inclusion and exclusion criteria. If these 2 reviewers had different opinions a discussion was held with a 3rd reviewer to resolve the matter. Literature information

Table 1. Search Strategies for an Online Search of PubMed.

PubMed	#1. Search: (electroacupuncture [MeSH Terms] OR electroacupuncture [All Fields] OR electro-acupuncture [All Fields] OR "acupoint electrical stimulation" [All Fields]) #2. Search: ("failed back surgery syndrome" [All Fields] OR "failed back surgery syndrome" [MeSH Terms] OR "spinal surgery" [All Fields] OR "spine surgery" [All Fields] OR "spinal fusion" [All Fields] OR "spine fusion" [All Fields] OR "lumbar surgery" [All Fields] OR "back surgery" [All Fields] OR "spinal operation" [All Fields] OR "spine operation" [All Fields] OR "lumbar operation" [All Fields] OR "back operation" [All Fields] OR laminectomy [All Fields] OR laminectomy [MeSH Terms] OR "nerve root decompression" [All Fields] OR foraminotomy [All Fields] OR foraminotomy [MeSH Terms] OR discectomy [All Fields] OR discectomy [MeSH Terms] OR "postoperative syndrome" [All Fields]) #3. #1 AND #2

(authors and publication year), information about participants (number of patients in the intervention group/control group, age, sex, and duration of illness), primary outcome, secondary outcomes, and AEs were extracted from the selected studies. The standard guideline for reporting intervention in clinical trials of acupuncture (STRICTA) [19] was used to collect details on needling, treatment regimen, and control interventions. Two reviewers independently collected data and resolved any disagreement of opinion through discussion with a 3rd reviewer.

Study of risk of bias assessment

To assess the risk of bias of the RCTs in the selection of study subjects, 2 researchers used 7 items (random sequence generation, allocation concealment, blinding of participants, and investigators) of the Cochrane Risk of Bias (RoB) tool [20] by independently rating them as "high," "low," or "unclear" risk of bias. When the 2 researchers had different opinions, they reached an agreement through discussion, and if necessary, a discussion with a 3rd researcher was held.

Data synthesis

To summarize the effect of selected studies via meta-analysis, the risk ratio was used for a dichotomous variable, the standardized mean difference (SMD) was used for continuous variables, and a 95% confidence interval (CI) was used in the analysis using Comprehensive Meta-Analysis Version 3.0 (Biostat Inc., Englewood, NJ, UES). Hedge's g was calculated and analyzed to prevent Cohen's d overestimation of the effect size because of the small sample sizes of the studies included in this review [21]. The effect size was interpreted as small when Hedge's g was 0.2-0.5, medium when it was 0.5-0.8, and large when it was ≥ 0.8. Among the selected studies, those with similar study design (such as interventional methods and evaluation tools) were assigned into 1 of 2 groups. Meta-analysis was employed based on the VAS and ODI scores as the measurement of therapeutic effects. A test of Higgins I^2 homogeneity was performed to determine heterogeneity between the studies and within the groups, which demonstrated $I^2 \leq 40\%$ suggesting no significant heterogeneity. I^2 30-70% is suggestive of moderate heterogeneity, I^2 50-90% suggests considerable heterogeneity, and $I^2 \geq 70\%$ suggests high heterogeneity [22]. When I^2 was < 50% and each study was considered comparatively homogeneous, the fixed-effects model was used for meta-analysis. When I^2 was ≥ 50%, which demonstrated heterogeneity, the random-effects model was used to synthesize the data for the study.

Reporting bias assessment

To assess the publication bias (because of sample size), the funnel plot was examined via visual inspection, and Egger's test was performed using Comprehensive Meta-Analysis Version 3.0 (Biostat Inc., Englewood, NJ, UES). Symmetrical and bilateral distribution of funnel plots for pooled data estimates that a straight line indicates absence of bias, and a $p > 0.05$ using Egger's test was considered an absence of publication bias [23]. However, based on the Cochrane Handbook for Systematic Reviews of Interventions, publication bias was not assessed if fewer than 10 studies were included in the analysis [20].

Certainty assessment

To evaluate the quality of evidence in each study included in the meta-analysis, the Grading of Recommendation Assessment, and the Development and Evaluation (GRADE) method for the GRADE PRO tool (http://gradepro.org/) was used [24]. The quality of evidence of RCTs was defined as high quality, moderate, low, or very low quality with limitations in the study design or execution (risk of bias), inconsistency of results (unexplained heterogeneity), indirectness of evidence, imprecision (sparse data), and publication bias.

Results

Study selection

Eight databases were searched, and a total of 129 studies were retrieved. Of these studies, 30 were retrieved from PubMed, 26 from CENTRAL, 39 from CNKI, 1 from J-STAGE, and 34 from Korean databases. Thirty-four duplicates were excluded. The titles and abstracts of the 95 studies were screened, and 77 studies, including 19 studies that were not related to FBSS or EA, 37 non-RCTs, 15 non-human studies, and 6 protocol studies, were excluded. The full manuscripts of 18 studies were reviewed, and a total of 11 studies were excluded. There were 3 studies excluded in which the therapeutic effect of EA could not be evaluated because the intervention group had EA combined with other methods and the control group received EA (2 studies of Herbal medicine and

1 of other method), 4 studies of the analgesic effect of EA during surgery, 3 studies using EA to control pain which developed due to surgery, and 1 study using EA for the rehabilitation process after spine surgery. These 11 studies were excluded and 7 studies were included for the review and meta-analysis (Fig. 1).

Study characteristics

A total of 514 patients with FBSS were assessed from the 7 RCTs (Table. 2). A total of 258 subjects were allocated to the intervention group, receiving either EA combination therapy [25-27] or EA alone [28-31], and 256 subjects were allocated to the control group, receiving conventional treatment (CT). Of the 7 studies, 5 were conducted in China [26,28-31] and 2 were conducted in South Korea [25,27]. All studies were conducted within the last 5 years, except for the study by Xin et al [31].

All RCTs were 2-arm parallel trials, and 3 used EA combined with CT as the intervention group [25-27] and CT as the control group to compare the effectiveness of EA. The other 4 studies [28-31] compared intervention groups that received EA alone with control groups that received CT.

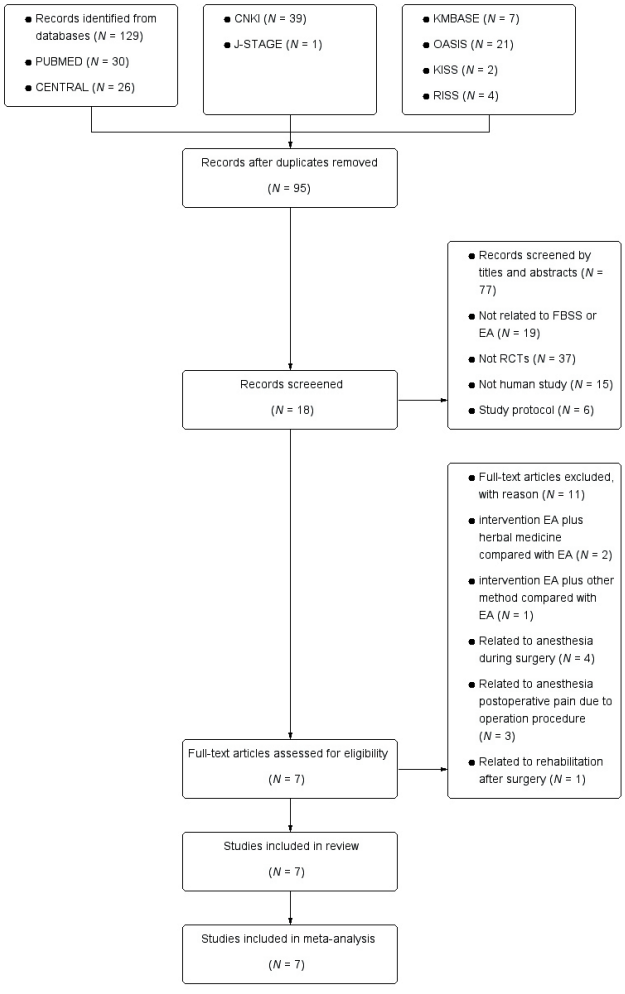

Fig. 1. Flow diagram of the study selection process of this review.

Among the studies investigating the effectiveness of EA combined with CT [25-27], Heo et al [25] used physical therapy (PT) and a standardized educational program as CT; Ding et al [26] used Western medication (W-med) and functional exercise (Exe) in the control group; and Heo et al [27] used W-med, PT, and Exe in the control group. Four studies [28-31] compared the effectiveness of EA alone with CT; Xie et al [28] used MA, PT, and W-med together with Exe as the control group; Cao [29] compared EA and W-med; Qi et al [30] used H-med as the control group; and Xin et al [31] used caudal injection as a comparator to EA.

Two studies [26,29] included patients who underwent percutaneous endoscopic lumbar discectomy, while 2 [28,30] included patients who underwent percutaneous transforaminal endoscopic discectomy. Three studies [25,27,31] did not have limitations on the type of surgery. Two studies [25,27] were performed in patients who had persistent pain for 3 weeks or longer after surgery, and the other 5 studies [26,28-31] were performed in patients who had persistent low back or leg pain immediately after spine surgery, the same as that before surgery.

All studies evaluated the VAS as a measure of primary outcome, and the secondary outcome measurements included the ODI, EQ-5D, British Medical Research Council's scale (BMRC), JOA, and TER.

Details of interventions

The STRICTA guidelines for reporting clinical trials of acupuncture [19] were used to present information related to the interventions of the 7 RCTs, to be reviewed in this study (Table. 3). Four studies [25-27,29] provided treatment to the intervention groups for 4 weeks, of which 2 [25,27] provided treatment 2 times a week for 4 weeks, 1 study [26] provided treatment once a day for 4 weeks, and another study [29] provided treatment for a total of 2 sessions: 10 days of treatment followed by 4 days without treatment for each session. There was 1 study [28] that provided treatment once a day for 12 weeks, and another study [31] provided treatment 3 times a week for 8 weeks. The study by Qi et al [30] had the shortest duration of treatment which was once a day for 20 days.

Of the 7 included studies, except for 1 study [29], EX-B2 points were used as acupuncture points [25-28,30,31], and BL23, GB30, BL40, BL34, ST36, and Ashi-points were used instead of EX-B2 points in the remaining study [29]. Of the 6 studies [25-28,30,31] that used EX-B2 points, 2 studies [25,27] used bilateral L3, L4, and L5 EX-B2 points, and 3 studies [26,28,31] used EX-B2 acupoints at the level where the condition/disease was located, and 1 study [30] made no special reference to it.

Various types and lengths of needles were described in many studies, however, several studies did not provide descriptions of needle characteristics. Additionally, multiple studies did not mention the depth the needle was inserted or elicitation of de qi.

In terms of EA methods, 4 studies [25,27,28,31] reported that an electrical current was passed between the bilateral EX-B2 points, although the rest of the studies did not describe the location. The frequency of the electrical current was 50 Hz in 2 studies [25,27],

Table 2. Summary of Included Studies.

Author (y)	Sample size (included→analyzed)	TG sex and mean age (mean ± SD) CG sex and mean age (mean ± SD)	Type of surgery	Treatment intervention	Control intervention	Outcome measure	Result*	Adverse events
EA + Conventional treatment vs. Conventional treatment								
Heo (2021) [25]	108 (54/54) 108 (54/54)	M/F = 27/27 46 ± 12 M/F 26/28 46 ± 14	NR	EA + CT (PT, Edu)	CT (PT, Edu)	1) VAS 2) ODI 3) EQ-5D	(T/C, Baseline, 3 wks, 5 wks, 8 wks, 12 wks) 1) 61→51→43→46→45/62→59 (p < 0.01 †)→ 52 (p < 0.05)→53 (p > 0.05)→53 (p > 0.05) 2) 36→32→27→26→25/35→33 (p < 0.01)→29 (p < 0.05)→28 (p < 0.05)→ 26 (p > 0.05) 3) 0.74→0.79→0.8→0.82/0.71→ 0.77 (p > 0.05)→0.78 (p > 0.05)→0.79 (p > 0.05)	None
Ding (2020) [26]	69 (35/34) 69 (35/34)	M/F 21/14 38.17 ± 4.33 M/F 19/15 39.26 ± 4.79	PELD	EA + CT (Exe)	CT (W-med, Exe)	1) VAS 2) ODI 3) BMRC	(T/C, Baseline, 2 wks, 4 wks) 1) 5.49 ± 1.14→3.86 ± 0.79→2.18 ± 0.52/5.52 ± 1.08→4.29 ± 1.14 (p > 0.05)→3.83 ± 0.86 (p < 0.01) 2) 85.36 ± 7.03→59.88 ± 4.92→31.74 ± 5.13 84.67 ± 6.27→53.82 ± 5.56 (p < 0.01)→ 35.39 ± 5.21 (p < 0.01) 3) TG>CG (p < 0.01)	None
Heo (2018) [27]	39 (18/21) 30 (12/18)	M/F 9/9 58.9 ± 9.8 M/F 10/11 56.5 ± 9.4	NR	EA + CT (W-med, PT, Edu)	CT (W-med, PT, Edu)	1) VAS 2) ODI 3) EQ-5D	(T/C, Baseline, 4 wks, 8 wks, 12 wks) 1) 64.61 ± 14.9→51.78 ± 20.62→41.50 ± 24.75→41.78 ± 24.62/67.33 ± 10.33→ 60.24 ± 19.25 (p > 0.05)→58.24 ± 20.83 (p > 0.05)→53.00 ± 21.39 (p > 0.05) 2) 44.70 ± 15.42→33.78 ± 17.45→31.95 ± 18.57→29.67 ± 18.46/38.23 ± 14.5→34.19 ± 17.09 (p < 0.05)→32.47 ± 16.04 (p < 0.01)→28.60 ± 16.69 (p > 0.05) 3) 0.65 ± 0.13→0.71 ± 0.11→0.74 ± 0.15→0.73 ± 0.170.66 ± 0.15→0.72 ± 0.14 (p > 0.05)→0.73 ± 0.13 (p > 0.05)→0.74 ± 0.13 (p > 0.05)	None
EA VS Conventional treatment								
Xie (2020) [28]	120 (60/60) 120 (60/60)	M/F 30/30 50.82 ± 1.54 M/F 30/30 56.00 ± 1.44	PTED	EA	CT (MA, PT, W-med, Exe)	1) VAS 2) ODI	(T/C, Baseline, 1 wk, 2 wks, 4 wks) 1) 7.99 ± 0.06→1.72 ± 0.11→0.68 ± 0.08→ 0.30 ± 0.06/8.08 ± 0.04→1.90 ± 0.08 (p > 0.05)→1.02 ± 0.07 (p < 0.01)→0.65 ± 0.06 (p < 0.01) 2) 85.89 ± 1.01→14.97 ± 0.91→4.42 ± 0.69→1.10 ± 0.28/86.50 ± 1.12→20.43 ± 1.22 (p < 0.01)→10.37 ± 0.83 (p < 0.01)→ 5.84 ± 0.60 (p < 0.01)	None
Cao (2018) [29]	44 (22/22) 44 (22/22)	M/F 12/10 45.03 ± 8.96 M/F 13/9 45.92 ± 8.77	PELD	EA	CT (W-med)	1) VAS 2) JOA	(T/C, Baseline, 2 wks, 4 wks) 1) 6.00→4.00→2.00/7.00→5.50→ 4.00 (p < 0.05) (T/C, Baseline, 4 wks) 2) 14.50→24.00/14.00→20.00 (p < 0.01)	NR
Qi (2017) [30]	78 (40/38) 78(40/38)	M/F 30/10 38.54 ± 5.21 M/F 24/14 42.80 ± 5.75	PTED	EA	CT (H-med)	1) VAS 2) TER	(T/C, Baseline, 20 d) 1) 5.85 ± 3.09 ± 0.72/6.11 ± 0.78→4 .23 ± 0.61 (p < 0.05) 2) 82.5/71.1 (p < 0.05)	None
Xin (2009) [31]	56 (29/27) 56 (29/27)	M/F 27/29 48 (mean, SD not reported, not divided between TG & CG)	NR	EA	CT(CI)	1) VAS 2) TER	(T/C, Baseline, 8 wks, 1 y) 1) 5.0500 ± 1.8586→3.1500 ± 1.6925→ 1.4667 ± 1.4320/5.4833 ± 1.7245→ 2.8667 ± 1.4499→2.3667 ± 1.7217 (p < 0.05) 2) 89.7/66.7 (p < 0.05)	NR

* The inequality sign indicates that the results are favorable.
† All p-values are comparison figures between I/C.
BMRC, British Medical Research Council scale; C, control; CG, control group; CI, caudal injection; CT, conventional treatment; Edu, education; Exe, exercise; JOA, Japanese Orthopaedic Association score; MA, manual acupuncture; NR, not reported; ODI, Oswestry Disability Index; PELD, percutaneous endoscopic lumbar discectomy; PTED, percutaneous transforaminal endoscopic discectomy; PT, physical therapy; T, treatment; TER, total effective rate; TG, treatment group; UC, usual care; VAS, visual analog scale

Table. 3. Details of Interventions Involving Electroacupuncture.

Author (y)	Treatment period	Treatment frequency	Acupoint	Details of needling	Details of EA	Needle retaining time
Heo (2021) [25]	4 wks	2×/wk	Bilateral EX-B2 at L3, L4, L5 + max 9 Amps according to the patients' symptoms	0.25 × 40 mm filiform needle	Loc: through 4 EX-B2 at L3 and L5 Form: biphasic Fre: 50Hz	15 min
Ding (2020) [26]	4 wks	1×/d	Bilateral EX-B2 of disease segment	0.3 × 75 mm filiform needle 1 inch deep until de qi	Int: according to patient's tolerance level	30 min
Heo (2018) [27]	4 wks	2×/wk	Bilateral EX-B2 at L3, L4, L5 + 6-15 Amps according to the patients' symptoms	0.25 × 40 mm filiform needle	Loc: through 4 EX-B2 at L3 and L5 Form: biphasic Fre: 50Hz	15 min
Xie (2020) [28]	12 wks	1×/d	according to the area innervated by affected nerves L1 (EX-B2, BL22, GB30, BL40, GB29, LR12, LR11) L2 (EX-B2, BL23, GB30. BL40, GB29, ST31, SP11) L3 (EX-B2, BL25, GB20, BL40, GB29, ST32, SP10, LR9) L4 (EX-B2, BL25, GB20, BL36, BL40, GB31, ST34, ST36, GB34, SP9, SP6, KI3, SP4) L5 (EX-B2, BL26, GB20, BL40, SP9, GB39, ST44) S1 (EX-B2, BL27, GB20, BL40, BL39, BL57, BL56, BL59, BL60, GB42)	Insert needle until de qi	Loc: Bilateral EX-B2 Int: level until the de qi is obvious	15 min
Cao (2018) [29]	4 wks	1×/d for 10 d then 4 d rest	BL23, GB30, BL40, BL34, ST36, Ashi-point	0.3 mm × 1 cun, 2 cun needle	Form: Biphasic Fre: 2Hz/100Hz Int: according to the patient's tolerance level	30 min
Qi (2017) [30]	20 d	1×/d	EX-B2, BL23, BL17, GB30, BL54, BL40, GV3, Ashi-point + SI3 (for pain at the Governor Vessel line), LU7 (for pain at the bladder meridian line)	Insert needle until de qi	Form: Biphasic Int: according to the patient's tolerance level	30 min
Xin (2009) [31]	8 wks	3×/wk	Bilateral EX-B2 of disease segment	3 cun needle	Loc: Bilateral EX-B2 Form: continuous Fre: 2 Hz/40 Hz Int: according to the patient's tolerance level	45 min

AP, acupoint; form, waveform; Fre, frequency; Int, intensity; Loc, location; NR, not reported

2 Hz and 100 Hz alternately in 1 study [29], 2 Hz and 40 Hz alternately in 1 study [31], and was not mentioned in the rest of the studies.

In terms of the waveform of the electrical current used to perform EA, 4 studies [25,27,29,30] used biphasic waveforms with sparse and dense waves, 1 study [31] used a continuous waveform, and 2 studies [26,28] did not describe the waveform of the electrical current used for EA. The electrical current intensity was controlled according to the patient's level of tolerance in 4 studies [26,29-31]; the remaining 3 studies did not mention it.

Regarding needle retention time, needles were left inserted for approximately 15 minutes in 3 studies [25,27,28], for 30 minutes in 3 studies [26,29,30], and for 45 minutes in 1 study [31].

Risk of bias in studies

The risk of bias of the 7 RCTs reviewed in this study was assessed using the RoB Tool of Cochrane (RoB 1.0). Performance bias was determined as a high risk of bias in all studies, and other bias was determined as an unclear risk of bias in all studies. The results are summarized in Figs. 2 and 3.

Random sequence generation

Of the 7 studies, 2 studies [25,27] used the computer-generated random numbers method of allocating, and 1 study [28] performed randomization by using the random number table. Thus, the risk of bias was considered "low." However, the risk of bias of the other 4 studies was considered "unclear" because they did not mention randomization methods for sequence generation.

Allocation concealment

In 2 studies [25,27], the risk of bias was considered "low" because an independent 3rd party used central randomization to achieve allocation concealment. However, the risk of bias of the remaining

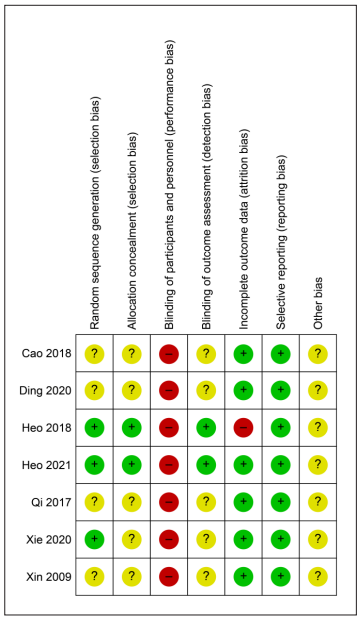

Fig. 2. Risk of bias summary: Review of researchers' judgements about each risk of bias item for each included study.

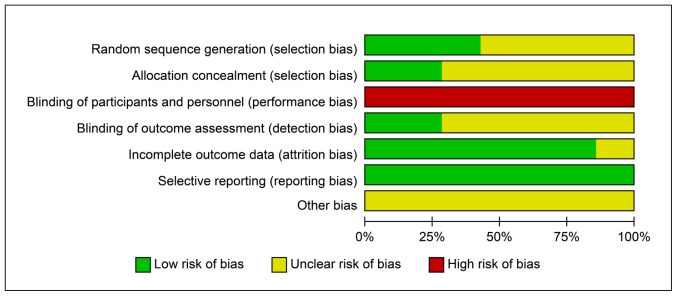

Fig. 3. Risk of bias graph: Review of researchers' judgements about each risk of bias item presented as percentages across all included studies.

5 studies was considered "unclear" because they did not mention allocation concealment methods.

Blinding of participants and personnel

The risk of bias of all 7 studies was assessed as "high" since they did not mention the method of the blinding process for EA treatment.

Blinding of outcome assessment

In 2 studies [25,27], the risk of bias was considered "low" because a well-trained 3rd party independently assessed the results, and in the remaining 5 studies, the risk of bias was considered "unclear" because they did not mention the method of blinding of the assessor.

Incomplete outcome data

Despite 1 study [27] with an incomplete outcome data set, the risk of bias was assessed as "low" because an intention-to-treat analysis was conducted in the study. In the remaining 6 studies, the risk of bias was assessed as "low" since their outcome data set was complete.

Selective reporting

The risk of bias of 2 studies [25,27] was assessed as "low" because both had applied protocols and described all the expected results. In the remaining 5 studies, the risk of bias was assessed as "low" since all the expected outcome data were reported.

Other bias

Although there may be additional risk of bias in all 7 studies, the risk of bias was assessed as "unclear" because of a lack of information on other biases.

Effectiveness of intervention

Electroacupuncture combined with conventional treatment

Three studies [25-27] applied treatment combining EA with CT in the intervention group for comparison with the CT-alone control group. Heo et al assessed outcomes using the VAS, ODI, and EQ-5D before treatment and at Weeks 3, 5, 8, and 12 [25]. After 4 weeks of treatment, the intervention group showed a significant reduction in the VAS score compared with the control group ($p < 0.01$), although it was not significant at the follow-up phase after the treatment ($p > 0.05$). The ODI scores showed statistically significant effects after 4 weeks of treatment, at Week 8, and during the follow-up phase in the intervention group compared with the control group, although it was not significant at Week 12 ($p > 0.05$). No significant results were observed in the EQ-5D scores for all observations compared with the control group. Ding et al assessed the VAS, ODI, and BMRC scores at baseline and after 4 weeks of treatment [26], showing that all scales were significantly improved in the intervention group compared with the control group ($p < 0.01$). Heo et al assessed the VAS, ODI, and EQ-5D scores before and after treatment, after 8 and 12 weeks of treatment, and at 2 follow-up visits [27]. The VAS and EQ-5D scores in the intervention group were not significantly different from those in the control group, and the ODI scores showed significant improvement when assessed at Weeks 4 and 8 ($p < 0.05$). In all studies, the VAS was used as a measure of the primary outcome, and the ODI was used as a measure of the secondary outcome; therefore, the VAS and ODI scores were used to conduct the meta-analysis. Since each study had different time points for assessing outcome measures, scores measured before and after treatment were used for analysis. The SMD was calculated using Hedges' g to correct for the overestimated effect size because of the small sample size used in the analysis. The Higgins I^2 homogeneity test was performed for 3 studies using the VAS, and resulted in $I^2 = 91.989$, which indicated statistically significant heterogeneity, and a random-effects model was applied accordingly. The results showed no significant difference in the reduction of the VAS scores (SMD = 1.098, 95% CI: -0.040-2.236, $p > 0.05$, $I^2 = 91.989$) between the intervention group and the control group (Fig. 4). The quality of

meta-analysis assessed by the GRADE tool was evaluated as "very low" downgrading by 3 steps from "high" because of the risk of bias, sparse data, and unexplained heterogeneity. The Higgins I^2 homogeneity test was performed for 3 studies using the ODI, and resulted in $I^2 = 0.000$, which indicated no statistical heterogeneity. A fixed-effects model was applied to conduct the meta-analysis accordingly. The results showed a significant improvement in the ODI scores (SMD = 0.680, 95% CI: 0.402-0.959, $p < 0.001$, $I^2 = 0.000$) in the intervention group (Fig. 5). The quality of this meta-analysis, assessed using the GRADE tool, was considered "low" downgrading by 2 steps from "high" because of the risk of bias and sparse data.

Electroacupuncture monotherapy

Four studies that compared the effectiveness of EA alone with the control group were included in the analysis. In the study by Xie et al, the VAS and ODI scores were assessed before treatment and at Weeks 1, 2, 4, 8, and 12, and the VAS and ODI scores of the intervention group were significantly reduced in all measurements compared with the control group ($p < 0.05$) [28]. Since this study was a long-term study with a 12-week treatment period, the scale scores generated after 4 weeks of treatment (which is the average treatment period of other studies), were used for the synthesis by taking bias into consideration. In the study by Cao [29], the VAS and JOA scores were assessed before treatment and at Weeks 2 and 4, and the results showed significant improvement compared with the control group (VAS: $p = 0.036$ JOA: $p = 0.007$). In the study by Qi et al [30], the VAS scores and TER were used to assess the outcomes before and after treatment, and both scores were significantly improved compared with the control group ($p < 0.05$). In the study by Xin et al [31], the VAS scores and TER were assessed before and after treatment, and at 1 year follow-up after treatment, the outcomes were compared and showed that all of them were significantly effective in the intervention group ($p < 0.05$). In this study, the scores after treatment were used for meta-analysis instead of the scores from the follow-up after 1 year. Since all 4 studies assessed the level of pain using the VAS score as the primary outcome, meta-analysis was conducted. The SMD was calculated using Hedges' g to correct the overestimated effect size because of the small sample size used, as performed in the meta-analysis of the effectiveness of EA combined with CT. The Higgins I^2 homogeneity test was performed for the 4 studies using the VAS, and resulted in $I^2 = 97.865$, which indicated that each study had a statistically significantly high level of heterogeneity. Accordingly, meta-analysis was conducted using a random-effects model. The results of the analysis showed a significant improvement in VAS score reduction (SMD = 2.063, 95% CI: 0.402-0.959, $p = 0.046$, $I^2 = 97.865$) in the EA-alone intervention group compared with the control group (Fig. 6). The quality of this meta-analysis, which was assessed by the GRADE tool, was "very low" downgrading by 3 steps from "high" because of the risk of bias, sparse data, and unexplained heterogeneity.

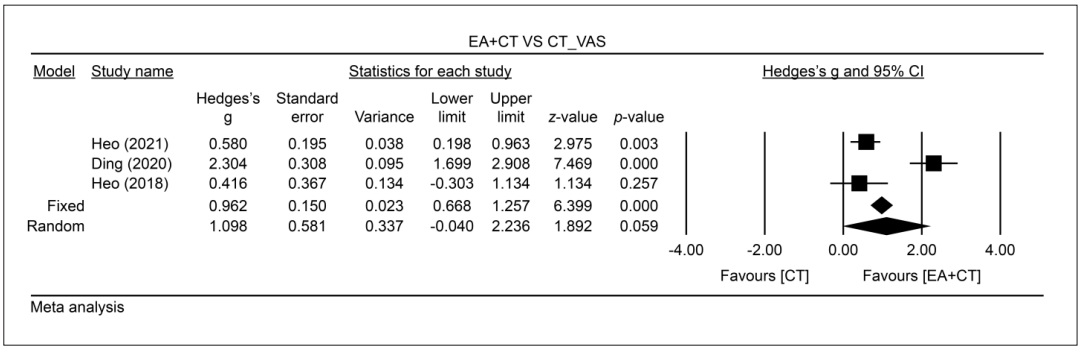

Fig. 4. Visual analog scale: Electroacupuncture combined with conventional treatment versus conventional treatment alone.

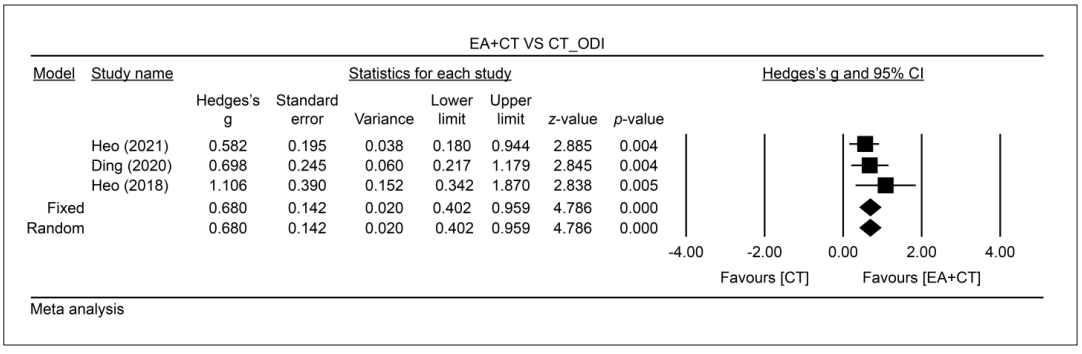

Fig. 5. Oswestry Disability Index: Electroacupuncture combined with conventional treatment versus conventional treatment alone.

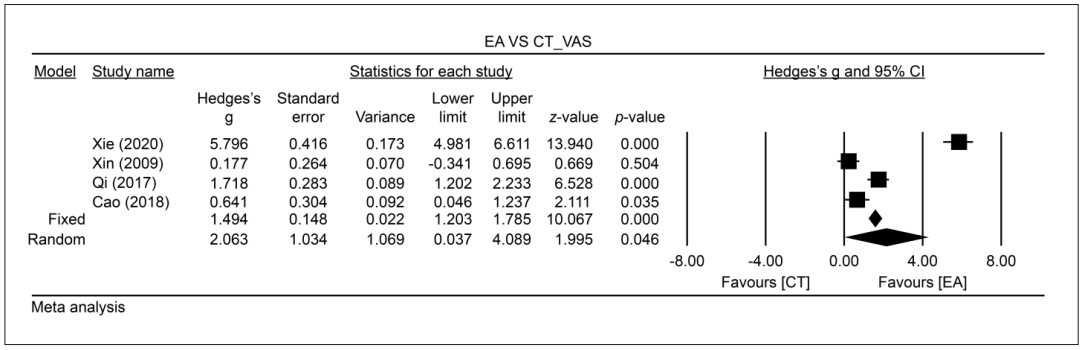

Fig. 6. Visual analog scale: Electroacupuncture monotherapy versus conventional treatment.

Adverse events

Five studies reported that there were no AEs because of EA [25-28,30], and the other 2 did not mention the AEs [29,31]

Reporting bias assessment

The number of studies used for meta-analysis in this study was 3 in the 1st instance, and 4 in the 2nd instance, therefore, publication bias was not assessed in accordance with the Cochrane Handbook for Systematic Reviews of Interventions because fewer than 10 studies were used [20].

Discussion

The National Health Insurance Service in Korea reported that general spine surgery has increased by 84% and endoscopic spine surgery has increased by 39% in 2015 compared with 2006 [32]. In Japan, in 2017, the number of patients with FBSS after surgery increased in proportion to the increased number of spinal surgeries performed [33]. The proportion of patients in Korea who underwent surgery within 10 years after lumbar discectomy has been reported as 16%, and after spinal stenosis as 14.2% [34,35]. Currently, a large number of patients with advanced age are seeking treatment in Korean medicine hospitals for FBSS because they want to avoid reoperation with the burden of the extra expenses, and the fear of reoperation failure [36]. As EA has been frequently used for chronic pain management in Korean medicine clinical practice, it is routinely used empirically in the treatment of patients with FBSS. This study was conducted to investigate the clinical effectiveness of EA in patients with FBSS.

In this study, 7 RCTs were selected for the review and meta-analysis. A total of 514 patients were treated for 56 days on average, regardless of the type of spinal surgery that the patients underwent. Seven studies were assigned to 1 of 2 groups for specific analysis: a group that compared an intervention group receiving EA combined with CT to a CT-alone control group, and a group that compared an EA-alone intervention group to a CT-alone control group.

For 3 studies [25-27], the reduction in the VAS score appeared largely effective, with an effect size of ≥ 0.8, although it was not significant ($p > 0.05$). For ODI scores, the 3 studies were not heterogeneous, and the effect on functional improvement in the EA-combined group was significantly higher than that of the control group ($p < 0.01$). Based on these results, we would suggest the use of EA combined with CT is effective in improving lumbar function, although the effect on pain reduction was not statistically significant. The results of the meta-analysis conducted using the VAS scores showed high heterogeneity between studies. This is thought to be due to the study design whereby the acupoints used for EA, and procedure time were different in the 3 studies. A large-scale study is needed to determine the statistical significance of the effect of EA in patients with FBSS.

In 4 studies [28-31] comparing EA alone with the control group that received CT, the meta-analysis showed a statistically significant reduction in pain in the intervention group with a large effect size ($p < 0.05$). However, the heterogeneity between the studies was significantly high, similar to the studies with the EA combined with CT intervention group. Based on the analyses, EA may be considered as a treatment for improving pain and lumbar function in patients with FBSS. However, the GRADE tool evaluation of meta-analysis showed low reliability in these results. Furthermore, all 7 studies were considered to have a high possibility of being biased. High-quality RCTs with a low risk of bias are needed in the future.

The treatments used in the 7 RCTs included in this study were analyzed in accordance with the STRICTA guidelines [19]. The most frequently used acupoint was EX-B2, followed by BL40, BL23, GB30, GB29, and GB20. In most of the studies, EX-B2 was used at the lumbar segments where the symptoms of FBSS occurred, and the needles were inserted into the acupuncture points along the meridians over the patient's lower limb radiating pain. In 4 studies [25,27,28,31], an electrical current was passed between the bilateral EX-B2 points. In addition, 4 studies [25,27,29,30] used biphasic waveforms using sparse and dense waves in terms of the EA waveform. In 4 studies [26,29-31], electrical current intensity was controlled according to the patient's tolerance level. Needles were left inserted for 15 minutes [25,27,28] and 30 minutes [26,29,30] to provide EA in 3 studies. Based on the results, it can

be considered that for treatment in clinical practice in patients with FBSS, needles should be inserted at the lumbar segments where the symptoms of LBP or lower limb radiating pain occurs. Additional needles should be inserted at the acupoints of the meridians that flow to the relevant area if accompanied by pain or decreased sensation. In addition, as described in a number of studies, passing an electrical current through the needles at EX-B2 points using biphasic waveforms and controlling the intensity up to the level that the patient can tolerate should be considered. However, several studies did not report the number of needles used, insertion depth, presence of de qi, and type of needles, and did not describe the work experience of the person who performed treatment, which leads to limitations on reapplication in clinical practice based on the STRICTA guidelines. It is necessary to report the treatment process in detail and in accordance with the STRICTA guidelines, such that it can be replicated in the clinical setting.

This study, by performing a systematic review and meta-analysis, attempted to derive a high level of clinical evidence, however, there are some limitations. Firstly, the included studies were conducted in two countries, China, and South Korea, therefore, if the results were reliable and not biased there would be a limit to the generalization of results to the global population. Secondly, the studies included were highly likely to be biased, as assessed by the Cochrane RoB and GRADE tools, resulting in low reliability of the overall study results, thus, caution should be exercised. Thirdly, since analysis was performed on EA combined with other methods in 3 studies [25-27] and EA alone in 4 [28-31] which were compared with the control group, it was difficult to confirm the clear benefit of EA itself. In addition, because the heterogeneity of each study was high, statistically insignificant results were observed in the meta-analysis, although an individual study reported a good overall effect. Fourthly, it is difficult to replicate the frequency or waveform and the acupoint used for EA because the studies were not the same, making it difficult to reach a consensus. High-quality RCTs that overcome the limitations mentioned are required to obtain more objective clinical evidence.

Conclusion

The present study showed that, for FBSS, EA-alone is effective in pain reduction and EA therapy combined with other treatments has a statistically significant effect on improvement in lumbar function, however, the reliability of these results is low. Safety and efficacy of EA treatment needs to be determined through good quality RCTs in the future.

Acknowledgments

The study protocol was registered on The International Prospective Register of Systematic Reviews (PROSPERO; registration no.: CRD42022319531)

Author Contributions

Conceptualization: DHS and JWL. Methodology: DHS. Formal investigation: DHS, KMS, HJJ, DK, JWY, JHO and JWL. Data analysis: DHS, JWY and JWL. Writing original draft: DHS. Writing – review and editing: DHS, KMS, HJJ, DK, JWY, JHO and JWL.

Conflicts of Interest

The authors have no conflicts of interests to declare.

Funding

None.

Ethical Statement

Not applicable.

Data Availability

All relevant data are included in this manuscript.

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