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Pain

PAIN

Multicentre randomised controlled clinical trial of electroacupuncture with usual care for patients with non-acute pain after back surgery

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Abstract

Background: The purpose of this study was to investigate the effectiveness and safety between electroacupuncture (EA) combined with usual care (UC) and UC alone for pain reduction and functional improvement in patients with non-acute low back pain (LBP) after back surgery.

Methods: In this multicentre, randomised, assessor-blinded active-controlled trial, 108 participants were equally randomised to either the EA with UC or the UC alone. Participants in the EA with UC group received EA treatment and UC treatment twice a week for 4 weeks; those allocated to the UC group received only UC. The primary outcome was the VAS pain intensity score. The secondary outcomes were functional improvement (Oswestry Disability Index [ODI]) and the quality of life (EuroQol-5-dimension questionnaire [EQ-5D]). The outcomes were measured at Week 5.

Results: Significant reductions were observed in the VAS (mean difference [MD] −8.15; P=0.0311) and ODI scores (MD −3.98; P=0.0460) between two groups after 4 weeks of treatment. No meaningful differences were found in the EQ-5D scores and incidence of adverse events (AEs) between the groups. The reported AEs did not have a causal relationship with EA treatment.

Conclusions: The results showed that EA with UC treatment was more effective than UC alone and relatively safe in patients with non-acute LBP after back surgery. EA with UC treatment may be considered as an effective, integrated, conservative treatment for patients with non-acute LBP after back surgery.

Clinical trial registration: KCT0001939.

Keywords: back surgery; electroacupuncture; integrative medicine; low back pain; postoperative pain; randomised controlled trial

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Low back pain (LBP) is a common health problem that most people experience in their lives.[1] According to the Global Burden of Disease 2010 study, LBP was ranked sixth in terms of the burden on society amongst 291 conditions.[2] Acute LBP usually subsides within 6 weeks.[3] However, in carefully selected cases, patients may be considered for spinal fusion surgery if they have failed to respond to conservative treatment for more than 2 yr.[4]

Surgical treatment for LBP is expected to reduce pain and resolve the functional problems of the lumbar spine,[5] but some patients complain of persistent or recurrent pain after surgery and require reoperation.[6–8] According to a retrospective cohort study in South Korea, the reoperation rate after surgery for spinal stenosis is 14.2% at 5 yr.[9] Therefore, pain management is very important for patients after back surgery. Various conservative and invasive treatments have been applied for pain management after back surgery,[6–8] and a multidisciplinary approach, including exercise, physical therapy, and medication, should be considered.[7]

Electroacupuncture (EA) is a type of acupuncture technique that combines electrical stimulation and acupuncture treatment. EA is effective for LBP[10,11] and various other pain conditions, such as myofascial pain,[12] osteoarthritis of the knee,[13] and postoperative pain.[14] Therefore, EA is considered to be an appropriate treatment for LBP after back surgery; however, few RCTs have investigated the effectiveness and safety of EA combined with other conservative treatments for postoperative LBP. We conducted a pilot trial between 2013 and 2014 to compare EA with usual care (UC) and UC alone for patients with non-acute LBP after back surgery.[15] In the pilot study, EA with UC showed significant functional improvement compared with UC alone (P=0.0081).[16] Based on our pilot study, we planned this comparative, pragmatic, and confirmative multicentre RCT combined with qualitative research and a cost-effectiveness analysis. The purpose of this RCT was to access the effectiveness and safety of EA with UC compared with UC alone for patients with non-acute LBP after back surgery.

Methods

Study design

Study flow

This multicentre, randomised, assessor-blinded active-controlled trial was conducted at three hospitals in South Korea. Participants were recruited through bulletin boards in hospitals or hospital websites. One hundred and eight participants were randomly divided into the EA with UC group or the UC alone group before the first treatment session. The treatment was continued for 4 weeks (twice per week; eight sessions in total), and the follow-up assessments were conducted at 4 and 8 weeks after the end of treatment. This study is registered (Clinical Research Information Service: KCT000 1939), and the protocol of this trial has previously been published.[17] The CONSORT checklist is provided in Supplementary Appendix A.

Ethics

This multicentre RCT was approved by the institutional review boards (IRBs) of the three participating hospitals: Pusan National University Korean Medicine Hospital (IRB approval number: 2016003), Kyung Hee University Oriental Medicine Hospital at Gangdong (IRB approval number: KHNMC OH 2015-10-002), and Jaseng Hospital of Korean Medicine (IRB approval number: KNJSIRB2016-025). All participants in the study voluntarily participated and written informed consent was obtained.

Study participants

Participants were included if they met the following criteria: (i) aged between 19 and 70 yr; (ii) persistent or recurring LBP after back surgery, irrespective of leg pain, lasting 3 weeks or more; (iii) a pain score ≥50 mm on the VAS; and (iv) voluntarily agreed to participate in the trial and presented written informed consent.

Participants were excluded if they met the following criteria: (i) a serious disease(s) that may have potentially exacerbated LBP, (ii) existence of severe neurological symptoms or progressive neurological deficits, (iii) pain that was not a result of spine or soft tissue disease(s), (iv) chronic disease(s) that may potentially influence the effects of treatment or analysis of the treatment result, (v) those for whom acupuncture was potentially inappropriate or unsafe, (vi) pregnant or planning to become pregnant, (vii) psychiatric disease(s) or currently being treated for a psychiatric disease(s), and (viii) currently participating in other clinical studies.

Randomisation and allocation concealment

Participants were randomly allocated at a 1:1 ratio to the two groups using centre-stratified block randomisation (block sizes of 4 and 8). Allocation concealment was achieved using sealed opaque envelopes.

Blinding

Blinding of practitioners and participants could not be conducted because of the distinct characteristics of the acupuncture treatment, including EA; consequently, blinding was only conducted for the outcome assessment.

Treatment

EA with UC group

The participants in the EA with UC group received a total of eight sessions (twice per week) of EA treatment in addition to UC treatment for 4 weeks. The EA treatment was performed using disposable stainless-steel needles (0.25 × 40 mm; Dong Bang Acupuncture, Inc., Seongnam, South Korea). The Jia-ji points (six acupuncture points; bilateral EX-B2 at L3, L4, and L5) and a maximum of nine additional acupuncture points were used. These additional acupuncture points were chosen according to the patient's symptoms. Electrical stimulation was applied to four Jia-ji acupuncture points (bilateral EX-B2 at L3 and L5) for 15 min at 50 Hz using an electrical stimulator (ES-160; ITO Co. Ltd, Tokyo, Japan). The participants in the EA with UC group also received UC treatment for the 4 week treatment period (see the following for details).

UC group

Participants in the UC group received physical therapy and a standardised educational programme. Physical therapy was administered twice per week during the 4 weeks. Interferential current therapy (ICT) (STI-300; StraTek Co. Ltd, Anyang, South

Korea; and EF-150; OG Giken Co., Okayama, Japan) and superficial heat therapy were applied for 15 min each. Additionally, the participants received a standardised education on LBP through a 20 min video and a brochure.

Permitted and prohibited concomitant treatments

Conventional pharmacological or non-pharmacological treatments associated with post-surgical LBP were allowed. However, any invasive procedures, such as injections and surgery, were prohibited during the study period.

Education for standardisation of the study procedures

The treatment and outcome assessment were conducted by Korean medical doctors with more than 3 yr of clinical experience. To standardise the study procedures, the practitioners and outcome assessors were trained based on pre-established standard operating procedures (SOPs) before participating in the study.

Outcome measurements

Primary outcome

The primary outcome was the pain intensity evaluated by the VAS, for which 0 points indicated no pain and 100 points indicated intolerable pain. The VAS was assessed at Weeks 3, 5, 8, and 12. The primary endpoint was the VAS at Week 5.

Secondary outcomes

Regarding secondary outcomes, disability related to back pain was assessed by the Oswestry Disability Index (ODI),[18] and the quality of life was assessed by the EuroQol-5-dimension questionnaire (EQ-5D)[19] using the validated Korean version. The ODI comprises 10 questions that are scored from 0 to 5, and higher scores indicate greater pain-associated disability.[20] The EQ-5D consists of five dimensions that are rated on a 3-point scale, where lower scores indicate better health status.[21] The participants were evaluated with the ODI at Weeks 3, 5, 8, and 12, and with the EQ-5D at Weeks 5, 8, and 12. Changes in permitted conventional treatments were recorded at each visit.

Adverse events

Any adverse events (AEs) were monitored and recorded at every visit.

Statistical analyses

Sample size calculation

A suitably powered full-scale sample size was estimated from the mean difference (MD) and standard deviation of the VAS score for LBP (14.02 [SD 22.12] mm) between the EA with UC group and the UC alone group, as described in our previous pilot study.[16] The sample size of this study was 108 patients (the size of each group was calculated to be 54; the data were two sided, with a 5% significance level, 80% power, and a 25% dropout rate).

Statistical analysis

Statistical analysis was conducted using an intent-to-treat (ITT) analysis. The ITT data set consisted of all participants who received treatment at least once and who were evaluated for the primary outcome at least once. Multiple imputation was used for missing data. An interim analysis was not conducted. An independent *t*-test was conducted for continuous data, and a χ^2 test or Fisher's exact test was used for categorical data. In this study, analysis of covariance was performed, which adopted the group as a fixed factor and baseline scores as covariates to analyse primary and secondary outcomes. Additionally, repeated-measures analysis of variance (RM ANOVA) was also performed to analyse the differences in the change trends between the groups over time. A safety assessment was conducted for all AEs that occurred throughout the study. The incidence of AEs and serious AEs (SAEs) were summarised by group and analysed by Fisher's exact test. All statistical analyses were carried out with SAS version 9.4 (SAS Institute, Inc., Cary, NC, USA). The significance level for the analyses of outcome assessments was 0.05.

Results

Participant disposition and characteristics

Participants were recruited beginning in June 2016, and the last follow-up visit was in May 2017. Of the 109 participants screened, one participant withdrew informed consent before randomisation; thus, 108 participants were equally allocated to the two groups. Nine participants in the EA with UC group dropped out because of withdrawal of informed consent (n=6), AEs or SAEs (n=2), or protocol deviation (n=1). Nine participants in the UC alone group dropped out because of withdrawal of informed consent (n=4) or AEs or SAEs (n=5) (Fig. 1).

The detailed baseline patient characteristics are presented in Table 1. No meaningful differences were observed between the two groups in any of the patient characteristics, including age, sex, height, weight, diagnosis, and baseline scores. Lumbar herniated intervertebral discs (HIVDs) (32 in the EA with UC group and 35 in the UC alone group) were the most common condition, and some participants (eight in the EA with UC group and six in the UC alone group) had multiple diagnoses (e.g. spinal stenosis with HIVD, spinal stenosis with spondylolisthesis, or HIVD with spondylolisthesis).

Pain intensity

Significant reductions in VAS scores were found in the EA with UC group compared with the UC alone group at Weeks 3 and 5 (MD −7.14, 95% confidence interval [CI] −12.25 to −2.02, P=0.0063; and MD −8.15, 95% CI −15.55 to −0.74, P=0.0311, respectively). Insignificant differences were observed between the two groups at Weeks 8 and 12 (P=0.1498 and P=0.1075, respectively) (Table 2; Fig. 2). The RM ANOVA showed no significant differences in interaction (time × group) effect (P=0.2495) for VAS (Fig. 2).

Functional improvement

Statistically significant differences in functional improvement as assessed by the ODI were observed at Weeks 3, 5, and 8 (MD −3.44, 95% CI −6.76 to −0.12, P=0.0424; MD −3.98, 95% CI −7.90 to −0.07, P=0.0460; and MD −5.38, 95% CI −9.64 to −1.13, P=0.0132, respectively). An insignificant difference was observed between the groups at Week 12 (P=0.1360) (Table 2; Fig. 2). The RM ANOVA revealed significant differences in interaction (time × group) effect (P=0.0426) for ODI, and the *post hoc*

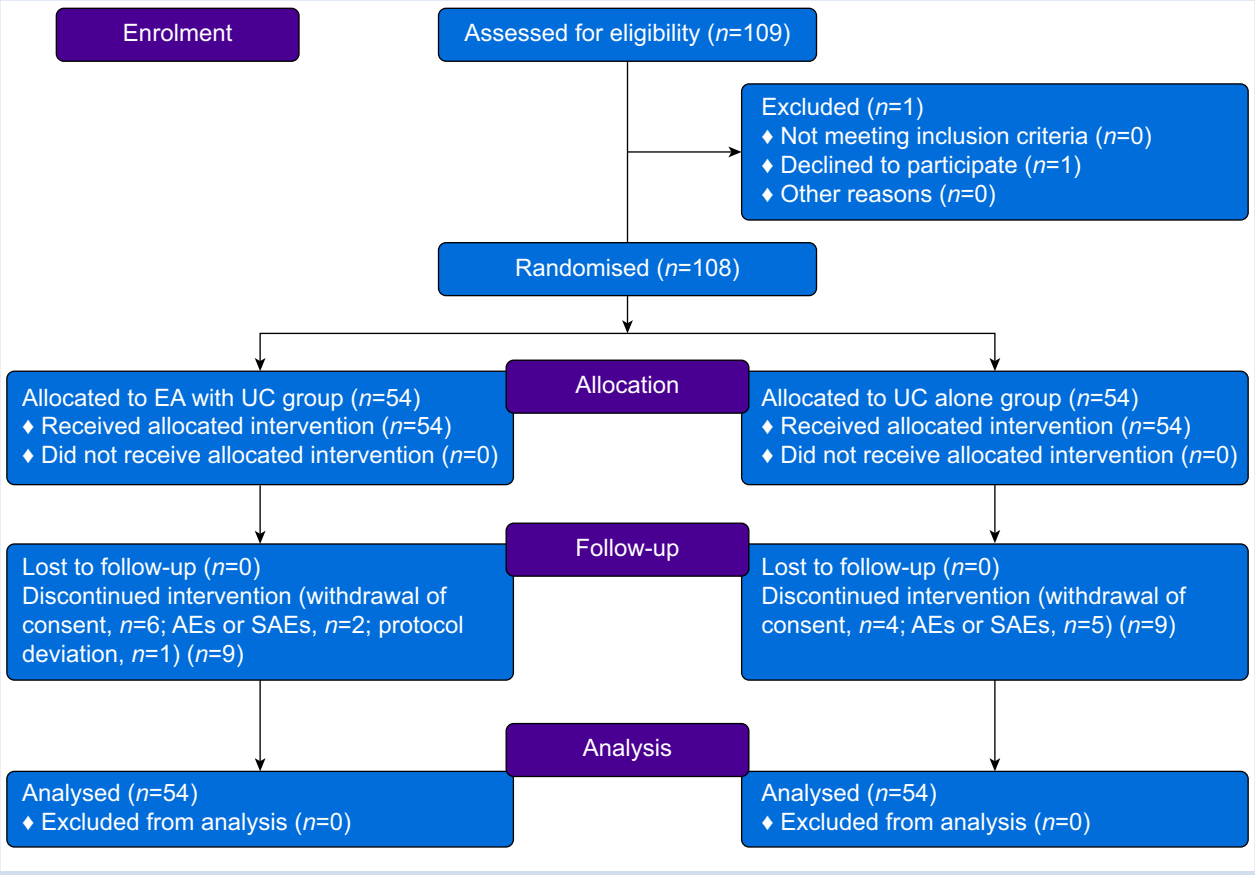

Fig 1. Study flow chart. AE, adverse event; EA, electroacupuncture; SAE, serious adverse event; UC, usual care.

Table 1 Baseline patient characteristics. CI, confidence interval; EA, electroacupuncture; EQ-5D, EuroQol 5-dimension questionnaire; HIVD, herniated intervertebral disc; ODI, Oswestry Disability Index; SMD, standardised mean difference; UC, usual care. The age, height, weight, and outcomes are represented by the means (standard deviations).

Variable	EA with UC group (*n*=54)	UC alone group (*n*=54)	SMD (95% CI)
Age (yr)	46 (12)	46 (14)	−0.01 (−0.39, 0.36)
Sex, *n* (%)			
Male	27 (50.0)	26 (48.2)	−0.04 (−0.41, 0.34)
Female	27 (50.0)	28 (51.8)	
Height (cm)	166.7 (8.5)	165.8 (7.7)	0.11 (−0.27, 0.49)
Weight (kg)	67.3 (11.5)	66.0 (11.3)	0.11 (−0.27, 0.49)
Diagnosis, *n* (%)			
Lumbar HIVD	32 (59.3)	35 (64.8)	0.17 (−0.21, 0.55)
Spinal stenosis	7 (13.0)	6 (11.1)	
Fracture	2 (3.7)	5 (9.3)	
Spondylolisthesis	2 (3.7)	0 (0.0)	
Scoliosis	1 (1.9)	2 (3.7)	
Cauda equine syndrome	2 (3.7)	0 (0.0)	
Multiple diagnoses	8 (14.8)	6 (11.1)	
Outcomes			
VAS (mm)	61 (14)	62 (12)	−0.08 (−0.46, 0.30)
ODI (%)	36 (15)	35 (15)	0.08 (−0.30, 0.46)
EQ-5D	0.74 (0.14)	0.71 (0.13)	0.21 (−0.16, 0.59)

Table 2 Primary and secondary outcome measures. CI, confidence interval; EA, electroacupuncture; EQ-5D, EuroQol 5-dimension questionnaire; ODI, Oswestry Disability Index; UC, usual care. *Least-squares mean difference using the analysis of covariance (ancova). †P-value by ancova. ‡P<0.05.

Variables	EA with UC group (n=54) Mean (95% CI)	UC alone group (n=54) Mean (95% CI)	Mean difference (95% CI) †	P-value ‡
VAS [mm]				
Baseline	61 (57, 65)	62 (58, 65)		0.6843
Week 3	51 (46, 55)	59 (55, 63)	−7.14 (−12.25, −2.02)	0.0063*
Week 5	43 (38, 49)	52 (46, 57)	−8.15 (−15.55, −0.74)	0.0311*
Week 8	46 (39, 52)	53 (47, 58)	−5.90 (−13.97, 2.16)	0.1498
Week 12	45 (39, 51)	53 (47, 59)	−6.65 (−14.76, 1.46)	0.1075
ODI [%]				
Baseline	36 (32, 40)	35 (31, 39)		0.6778
Week 3	32 (28, 35)	33 (28, 37)	−3.44 (−6.76, −0.12)	0.0424*
Week 5	27 (24, 30)	29 (25, 32)	−3.98 (−7.90, −0.07)	0.0460*
Week 8	26 (22, 30)	28 (24, 32)	−5.38 (−9.64, −1.13)	0.0132*
Week 12	25 (21, 28)	26 (23, 30)	−3.19 (−7.40, 1.01)	0.1360
EQ-5D				
Baseline	0.74 (0.7, 0.78)	0.71 (0.68, 0.75)		0.2602
Week 5	0.79 (0.76, 0.81)	0.77 (0.74, 0.8)	0.015 (−0.019, 0.050)	0.3713
Week 8	0.8 (0.77, 0.83)	0.78 (0.75, 0.81)	0.011 (−0.028, 0.051)	0.5645
Week 12	0.82 (0.78, 0.85)	0.79 (0.76, 0.82)	0.024 (−0.018, 0.066)	0.2585

P-values at Weeks 3, 5, and 8 were 0.0280, 0.0478, and 0.0074, respectively (Fig. 2).

Quality of life

No statistically significant differences were found in the EQ-5D scores between the two groups at Weeks 5, 8, and 12 (Table 2). The RM ANOVA showed no significant differences in interaction (time × group) effect (P=0.5516) for EQ-5D.

Permitted additional treatments

There was no significant difference in the use of additional treatment between the groups (one patient [1.9%] in the EA with UC group and three patients (5.6%) in the UC alone group; P=0.6179).

Safety

Fifty-three AEs were reported during the 1161 visits, and there was no significant difference in the incidence of AEs between the groups (29 [5.11%] AEs in the EA with UC group and 24 [4.05%] AEs in the UC alone group; P=0.4023). The SAEs reported in the EA with UC group included hospitalisation for traffic accidents (n=2), and those reported in the UC alone group included hospitalisation for appendicitis (n=1), cystitis (n=1), and aggravation of pain (n=3). None of the AEs had a causal relationship with the EA treatment.

Discussion

This is the first pragmatic multicentre RCT to evaluate EA with UC treatment in patients with non-acute LBP after back surgery. The results of this pragmatic RCT indicate that EA with UC treatment is more effective than UC treatment alone for pain relief, as measured by the VAS pain intensity scores. The mean VAS score for LBP after back surgery decreased by 17.37 in the EA with UC group (a 28.63% decrease from baseline) compared with −9.90 in the UC alone group after 4 weeks of treatment (at Week 5) (P=0.0311). In addition, regarding the functional improvement of pain-related disability, as measured by ODI, the improvements in the EA with UC group were considerably greater than those in the UC alone group at Week 5 (P=0.0460). The change of 9.18 in the EA with UC group after the treatment period was an approximately 25.38% improvement from baseline. Additionally, the improvement of function was maintained at 4 weeks after the 4 week treatment (at Week 8), exhibiting a significant difference from the control group (P=0.0132). The incidence of AEs was not different between the EA with UC group and the UC alone group, and no AEs were causally related to EA treatment.

Postoperative pain can be caused by a variety of factors, including psychological issues and the progression of degenerative changes after surgery,[6–8] and some patients who underwent surgery required reoperations for reasons, such as postoperative complications, progressive degenerative changes, or persistent pain.[22] Pain management after back surgery can be approached through various conservative and invasive treatments.[6–8] Conservative management includes medications (such as NSAIDs, oral steroids, and opioids), physical therapy, and acupuncture.[7] However, most long-term and continuous medications for painful conditions frequently cause side-effects and complications.[23 24] NSAIDs increase the risk of gastrointestinal and cardiovascular problems.[23] In addition, opioid medications have common side-effects, including addiction, physical dependence, nausea, and constipation.[24] Therefore, to achieve pain relief whilst minimising the side-effects of medications, a multidisciplinary approach should be considered.

Acupuncture is generally known to be effective for treatment of chronic LBP,[25] and is cost-effective for patients with sub-acute or chronic LBP.[26] The clinical practice guideline published by the American College of Physicians recommends acupuncture treatment for patients with acute, sub-acute, and chronic LBP.[27] According to systematic reviews and meta-analyses, acupuncture and related techniques improve acute postoperative pain and reduce opioid consumption.[28,29] In our systematic review, acupuncture treatment for acute pain after back surgery showed positive results compared with sham

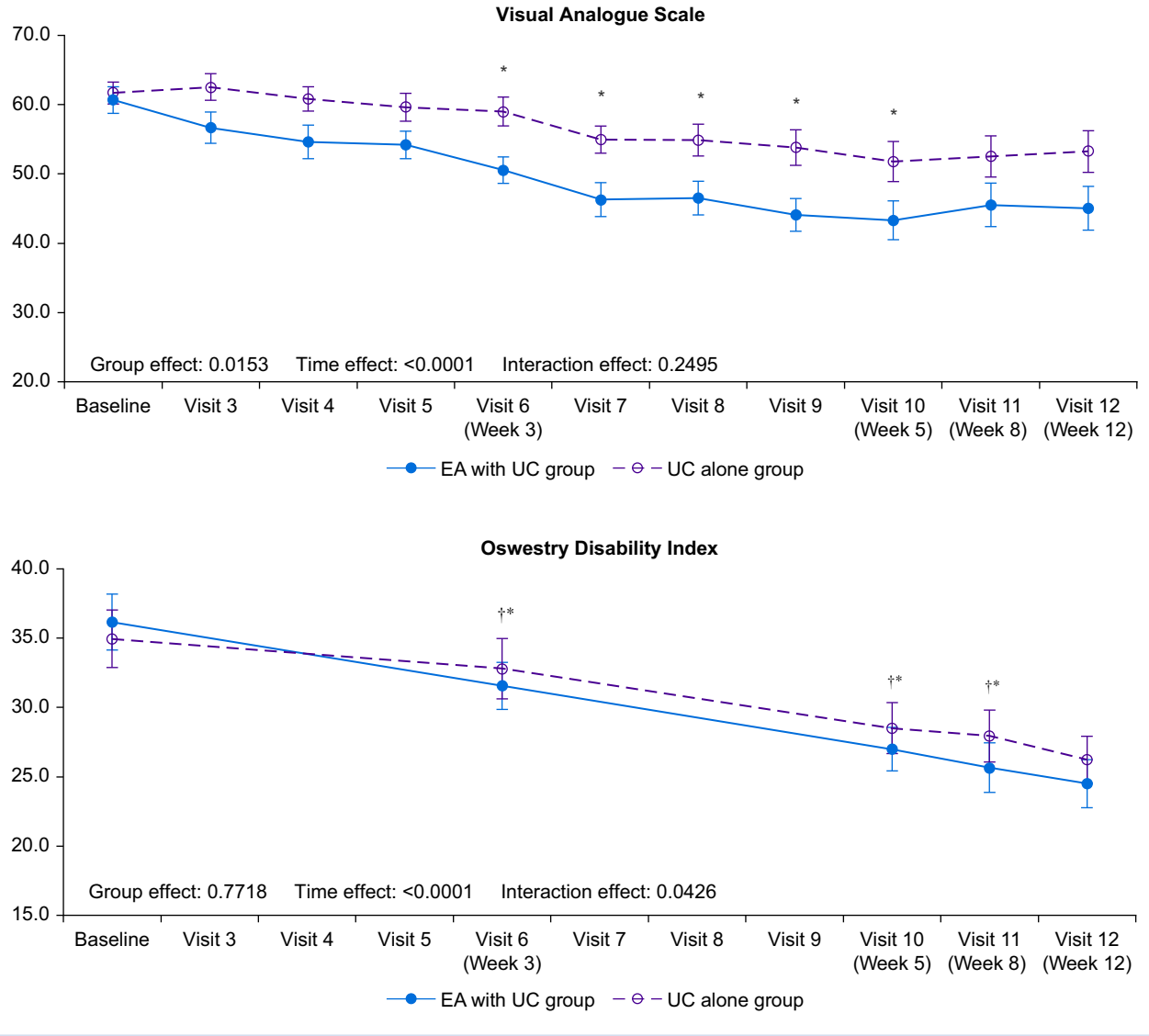

Fig 2. Primary and secondary outcome measures. EA, electroacupuncture; ODI, Oswestry Disability Index; UC, usual care. *$P<0.05$; P-value by analysis of covariance. †$P<0.05$; *post hoc* test for repeated-measures analysis of variance. Error bar indicates standard error.

acupuncture.[30] In a nationwide retrospective cohort study in South Korea, the rate of lumbar surgery was lower in the acupuncture group than in the control group (hazard ratio 0.633).[31] Electroacupuncture treatment, a type of acupuncture technique, is a very commonly used treatment method in clinical practice in South Korea. Additionally, it is effective for the management of various types of pain, including LBP,[10,11] myofascial pain,[12] osteoarthritis of the knee,[13] chronic discogenic sciatica,[32] painful diabetic peripheral neuropathy,[33] and postoperative pain.[14,34] Based on these findings, we conducted a pilot trial to evaluate the feasibility and estimate the proper sample size for a confirmative RCT in patients after back surgery. The results of our pilot study showed a significant decrease in the ODI (P=0.0081) between the EA with UC and UC alone groups, although there was no significant difference in the VAS or EQ-5D scores.[16] Based on the clinical reality that functional improvement is unlikely to occur without pain reduction, we concluded that a large-scale clinical study is needed to confirm the effectiveness of EA combined with UC for pain reduction and functional improvement for patients with postoperative back pain. The results related to the reduction in pain and the recovery of function are clinically meaningful in this multicentre RCT study. The minimal clinically important difference (MCID) for LBP, as reported in a previous study,[35] was 18–19 points on the VAS and 10 points on the ODI. In the results of this study, the VAS score change of 17.37 and the ODI score change of 9.18 in the EA with UC group were not only statistically significant, but also similar to the MCID. It can be concluded that EA with UC treatment can provide a significant clinical benefit to patients with postoperative back pain.

In this study, UC treatment included physical therapy, such as ICT and superficial heat therapy, and a standardised educational programme that included exercise. We selected

UC treatment, which is the most commonly applied treatment for patients with LBP, as a control to reflect actual medical reality according to the Korean Health Insurance Review and Assessment statistics.[36] In addition, conventional pharmacological and non-pharmacological treatments were allowed throughout the study period to reflect the actual clinical circumstance. Additionally, based on a consensus amongst experts in this field, the treatment procedure of this trial was designed considering the clinical reality in South Korea, where it is common to treat non-acute LBP two to three times per week. The results of this study showed that UC alone was effective for pain reduction and functional improvement from baseline to 4 weeks of treatment (P=0.0008 and P=0.0162, respectively), but EA with UC treatment was more effective than UC alone in reducing pain and recovering function at every assessment. In addition, three participants in the UC alone group were admitted to the hospital for aggravation of pain. Therefore, EA with UC treatment is more effective than UC alone and relatively safe for patients with non-acute postoperative back pain.

These conclusions are based on the establishment of evidence of the effectiveness and safety of EA with UC treatment for LBP after back surgery. Electroacupuncture with UC treatment could be considered as an effective, integrated, conservative treatment for non-acute postoperative back pain.

Strengths and limitations

This study was a multicentre RCT based on the results of our pilot study. We used appropriate randomisation, validated assessment tools, and SOPs. Usual care treatment was selected as the control to reflect real-world clinical conditions. Because qualitative research and economic evaluations were conducted in this study, the results provide various perspectives on patients with non-acute postoperative back pain. This study had several limitations. First, the practitioners and participants were not blinded because neither a placebo nor sham EA was used as a control. Second, our recruitment method, relying on bulletin boards in hospitals or hospital websites, is a possible source of confounding, as individuals who respond to these types of advertisements are likely to be a self-selecting or specific subgroup of patients with chronic back pain. Third, only subjective outcomes were used to assess pain and function; therefore, the mechanisms of EA treatment were not confirmed in the present study. Additionally, we could not stratify the results according to the type of surgery. Therefore, further studies considering the type of surgery are needed. Additional studies are required to evaluate the effectiveness and safety of EA with UC treatment during the acute phase after back surgery.

Conclusions

In conclusion, the results of this multicentre RCT present evidence of the effectiveness and safety of EA with UC treatment for pain relief and functional improvement in patients with LBP after back surgery. EA with UC treatment could be considered as an effective, integrated, conservative treatment for non-acute LBP after back surgery.

Authors' contributions

Study design: IH, B-CS, E-HH, N-KK, D-WS, J-HC, K-WK, I-HH, M-RK, J-HL, S-YJ, K-MS
Overall design and trial execution process: K-MS
Statistical analysis: OK
Drafting of paper: IH, K-MS
All authors have read, revised, and approved the final paper in its current form.

Declarations of interest

The authors declare that they have no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2020.10.038.

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