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The Use of Electro-Acupuncture in Conjunction with Exercise for the Treatment of Chronic Low-Back Pain

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ABSTRACT

Objectives: To determine the effect of a series of electro-acupuncture (EA) treatment in conjunction with exercise on the pain, disability, and functional improvement scores of patients with chronic low-back pain (LBP).

Design: A blinded prospective randomized controlled study.

Subjects and interventions: A total of 52 patients were randomly allocated to an exercise group ($n = 26$) or an exercise plus EA group ($n = 26$) and treated for 12 sessions.

Outcome measures: Numerical Rating Scale (NRS), Aberdeen LBP scale, lumbar spinal active range of movement (AROM), and the isokinetic strength were assessed by a blinded observer. Repeated measures analysis of variance (R-ANOVA) with factors of group and time was used to compare the outcomes between the two groups at baseline (before treatment), immediately after treatment, 1-month follow-up, and 3-month follow-up. The level of significance was set at $p = 0.05$.

Results: Significantly better scores in the NRS and Aberdeen LBP scale were found in the exercise plus EA group immediately after treatment and at 1-month follow-up. Higher scores were also seen at 3-month follow-up. No significant differences were observed in spinal AROM and isokinetic trunk concentric strength between the two groups at any stage of follow-up.

Conclusions: This study provides additional data on the potential role of EA in the treatment of LBP, and indicates that the combination of EA and back exercise might be an effective option in the treatment of pain and disability associated with chronic LBP.

INTRODUCTION

Low-back pain (LBP) is a major health and economic problem in Western countries (van Tulder et al., 1997). At any given time, some 31 million people in the United States have low-back pain (LBP; Jensen et al., 1994), and one half of the working population in the United States have back symptoms each year (Vallfors, 1985). Other studies have put the annual incidence in the United States as high as 70% (National Institute for Occupational Safety and Health, 1997). In a local survey, 39% of adults in Hong Kong reported that they had had at least one episode of LBP since birth (Lau et al., 1995), and a telephone survey reported that the cumulative life prevalence and the 12-month prevalence of LBP in the Hong Kong

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population were 57% and 42%, respectively (Leung et al., 1999). Although there are no documented figures on the number of days sick leave and compensation costs related to LBP in Hong Kong, 66.8% of LBP subjects reported that their back pain was work-related (Leung et al., 1999).

The effectiveness of therapeutic interventions for the treatment of chronic LBP has not been convincingly demonstrated (Frymoyer, 1988; Spitzer et al., 1987). Acupuncture is anticipated as being a potentially useful treatment strategy to complement traditional Western medical management in alleviating the pain and disability associated with chronic LBP. There has been an increasing use of acupuncture in pain management (Woollam and Jackson, 1998), and acupuncture is now available as a treatment option in chronic pain clinics in many countries (Woollam and Jackson, 1998). Electro-acupuncture (EA) is based on conventional acupuncture, with the additional application of an electric pulse to meridians and acupoints in order to strengthen the effect. This method is generally used for analgesia and has become increasingly popular since the 1970s (Chan, 1974; Tsui et al., 2002). This modality of acupuncture has the advantages of standardized quantity and quality of stimulation by controlling the input current amplitude and frequency.

The reported efficacy of acupuncture for the management of chronic LBP in randomized controlled trials was reviewed (van Tulder et al., 1997) and it was found that the heterogeneity and poor methodological quality of the studies conducted made the validity of results obtained less convincing than they initially appeared. Although evidence of long-term pain relief after manual acupuncture and EA in chronic nociceptive (nonorganic) LBP compared to placebo was demonstrated (Carlsson et al., 2001), the effectiveness of EA in treatment of other forms of chronic LBP remains unclear. The effects of acupuncture and acupuncture plus back exercise have been compared (Song, 1993). However, the outcome measure was not properly controlled because the therapeutic effect was rated subjectively as cured, markedly effective, improved, and ineffective according to the degree of alleviation of sign and symptom (Song, 1993). Therefore, a well-designed randomized control trial with a larger sample size, valid acupuncture treatment, and outcome measures is needed to determine the effectiveness of EA in the management of chronic LBP. For ethical reasons, it was not feasible to include an untreated control in this study, and back exercise is used as is typically administered by physiotherapists, either alone or in combination with other methods of treatment for chronic LBP. No attempt is made to compare the efficacy of EA to more active approaches to treating chronic LBP patients (Kose et al., 1995; Torstensen et al., 1998). Consequently, the present randomized, assessor-blinded controlled clinical trial is designed to investigate the immediate and medium-term effects of back exercises alone (control group) or in conjunction with a series of EA treatment (experimental group) on the pain, disability and functional scores in patients with chronic LBP.

MATERIALS AND METHODS

Patients with chronic LBP satisfying the inclusion and exclusion criteria listed in Table 1 were recruited through referral from the medical officer in charge of the outpatient clinic of the Department of Orthopaedics and Traumatology, Kwong Wah Hospital, Hong Kong, during the period 2001–2002. As a detailed specific Western diagnosis cannot be made in the majority of patients with chronic LBP (Deyo and Phillips, 1996; Waddell et al., 1996), subjects included in this study were those with nonspecific back pain without any underlying pathophysiologic or anatomic problems identified during physical and radiologic examination (Hadler, 1993). Inclusion, exclusion, and withdrawal criteria are listed in Table 1. Patients fulfilling these criteria were asked to participate in the study, and the aims and procedure of the study were explained before written consent was obtained. Ethical approval from the Ethics Committee of the Hong Kong Hospital Authority and the Human Subject Ethics Subcommittee of The Hong Kong Polytechnic University was obtained prior to the start of the study. Blocked randomization of patients to ei-

Table 1. Inclusion, Exclusion and Withdrawal Criteria

Inclusion criteria
1. Chronic LBP
It was defined as a complaint of pain of the lower back below the 12th thoracic vertebrae with or without radiation with an onset of duration of 6 months or more
2. Age between 18–75 and of both genders
Exclusion criteria
1. Structural deformity (ankylosing spondylitis, scoliosis)
2. Lower limb fracture
3. Tumors
4. Spinal infection
5. Cauda equina syndrome
6. Pregnancy
7. Spinal cord compression
8. Subjects who were inability to keep the appointments
9. Receiving acupuncture treatment within the past 6 months
10. Receiving physiotherapy treatment within the past 3 months
Withdrawal criteria
1. Other acute orthopaedic or medical problems that hinder back exercise

LBP, lower back pain.

ther the exercise group ($n = 26$) or the exercise plus EA group ($n = 26$) was used in this study to minimize possible selection bias. Allocation of patients to the two groups was randomized and blinded, and patients were asked not to undergo any other types of therapy for LBP during the study period to avoid contamination of the results.

Treatment procedure

Back exercise group. Patients received physiotherapy in the form of a standard group exercise program led by the same physiotherapist. The program consisted of an hourly session each week for 4 consecutive weeks, and comprised the following back strengthening and stretching exercises:

- Warm up and stretching of back muscles × 10 minutes;
- Back extension exercise × 15 repetitions × 3 times with rest between (progress with adding arm weight);
- Abdominal exercise × 15 repetitions × 3 times with rest between (progress by repositioning the arms); and
- Cool down with stretching of back muscles × 10 minutes.

In addition, patients were advised on spinal anatomy and body mechanics, back care and postural correction, lifting and ergonomic advice, and behavioral modification, as well as a series of home exercises (15 minutes per day). Patients were instructed to perform the designated types of back exercise every day over the period of the study. Home exercise monitoring cards were given to patients for recording purposes, and an independent assessor checked the patient's compliance using these cards.

Back exercise plus EA group. The group exercise program was conducted by a blinded therapist in the same way as for the exercise group. In addition, EA was administered three times per week for 4 weeks by another physiotherapist certificated in acupuncture. The acupoints were chosen according to a summation of common points used in the literature reviewed along the Bladder and Spleen meridian (Coan et al., 1980; Edelist et al., 1976; Gunn et al., 1980; Lehmann et al., 1986; MacDonald et al., 1983; Thomas et al., 1994). These were the UB23 (Shenshu), UB25 (Dachangshu), UB40 (Weizhong), and SP 6 (Sanyinjiao) points (Fig. 1). Acupuncture was applied to the side on which patients reported pain. If the reported pain was bilateral, EA was applied to the more painful side. The patient was placed in a prone position and a sterilized disposable number 30 (0.3-mm diameter) 40-mm long needle was inserted and manipulated until a sensation of numb-

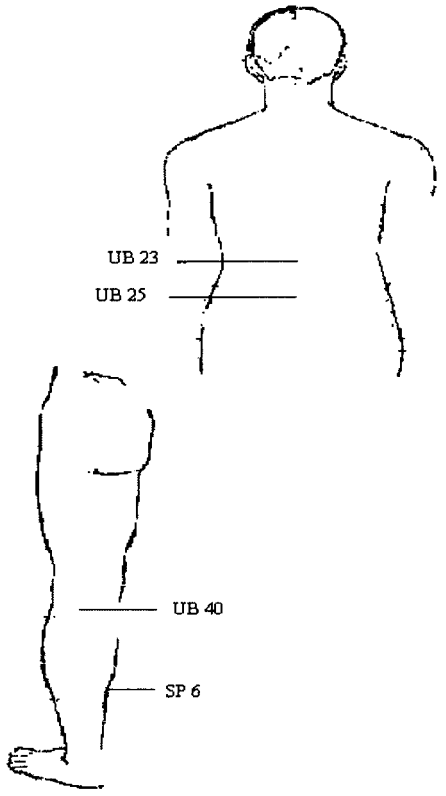

FIG. 1. The four acupoints, UB-23 (*Shenshu*), UB25 (*Dachangshu*), UB-40 (*Weizhong*), and SP-6 (*Sanyinjiao*), used in the study.

ness, tingling, heat, or distension at the site of needle insertion, known as *te chi* in Chinese Traditional Medicine, was obtained. The needle was then coupled to an electrical stimulator (Shanghai Medical Technology Co., Shanghai) at a frequency of 2 Hz as suggested by Han et al. (1981) for 30 minutes to allow endorphinergic analgesia to build up (Gabriel et al., 1985). The intensity of the stimulation was set at the level that the patient could tolerate and often with evoked visible muscle contractions. We applied the current with biphasic waveform (positive wave in the square form and negative wave in the triangle form with 0.5-ms pulse width) to the four selected acupoints in two pairs (i.e., UB-23/UB-25 pair and UB40/SP6 pair).

Collected data and outcome measures. All patients were assessed by a blinded observer who was not aware of the treatment allocation. The assessment was performed before and after the treatment series as well as at 1 and 3 months after the treatment. In this study, the primary outcome measures were:

(1) *Pain*—Numerical rating scale (NRS) was used to measure the average and the worst pain intensity during the last week on assessment, by asking the patient to rate his or her perceived level of pain intensity on a numerical scale from 0 to 10, with 0 representing one extreme (no pain) and 10 representing other extreme (pain as bad as it could be). This shows a high reliability in both literate and illiterate patients (Ferraz et al., 1990), and it has also been demonstrated that the NRS and visual analog scales (VAS) have correlation ranging from $r = 0.77$ to 0.91 (Downie et al., 1978).
(2) *Disability*—The Aberdeen LBP scale was used to measure low back disability, because it is the only LBP-specific functional disability scale that has been validated for use in Chinese subjects. It consists of a 19-item questionnaire that has been adapted to be appropriate for Chinese culture, and has a reported test-retest reliability of $r = 0.94$ ($p < 0.05$) with Cronbach α equal to 0.85. The correlation with the current generic 42-item questionnaire is 0.59. It assesses the health status of patients with LBP across several dimensions, including pain, physical impairments, and functional disability. Responses to the questions were summed and converted to a score percentage between 0 and 100, with 0 representing the least disabled and 100 the most severely disabled (Leung et al., 1999).

Secondary outcome measures used in this study were:

(1) *Lumbar spinal angular range of motion (ROM) in flexion-extension*—The angular ROM of the lumbar spine was measured using a Dualer Plus inclinometer (Jtech Medical Industries, Salt Lake City, UT). A pilot study showed the inclinometer to give reliable measurements, with intraclass correlation coefficients (ICC) model (1,1) of 0.90 for trunk flexion and 0.80 for extension. The device was secured to the patient at the sacrum and the thoracolumbar junction.

Each exercise was demonstrated by the investigator and then practiced by the patients. Two trials of flexion-extension were then carried out. The highest value generated was taken as representative for that movement.

(2) *The isokinetic trunk flexor and extensor strength*—The isokinetic trunk flexor and extensor strength were measured using a Cybex 6000TEF modular component isokinetic dynamometer (Lumex, Inc., Ronkonkoma, NY). Patients were measured standing with positioning standardized according to the manufacturer's recommendations. The axis of rotation was centered approximately at the intersection of the mid-axillary line and L5-S1, and the angular ROM was set at 5-degree extension and 60-degree flexion in all patients. Measurements were at an angular velocity of 60 degrees per second because this closely approximates to a number of daily activities (Motulsky, 1995). Five trial repetitions preceded measurements, where the same examiner asked the patient to move or pull "as hard and as fast as they could." Flexor peak torque percent body weight (FPTBW), extensor peak torque percent body weight (EPTBW), flexor total work percent body weight (FTWBW), and extensor total work percent body weight (ETWBW) at 60° per second were then measured over the following five repetitions.

Follow-up. Assessment was performed before (as baseline) and immediately after the treatment series. Follow-up assessment was at 1 and 3 months after the treatment series. The patients were reminded by either telephone or mail. Exercise level, analgesic consumption, and whether they had undertaken any other therapy for their LBP during the study were recorded, and all patients were also given a detailed self-administered questionnaire on their demographic information.

Statistical methods. Statistical analysis was conducted based on the intention-to-treat principle. Patients dropping out for reasons other than the treatment to which they had been randomly assigned were given the baseline registration scores for the missing timepoints. Patients dropping out because of the treatment to which they were randomly assigned were given the worst score registration (Torstensen et al., 1998). To determine the robustness of conclusions, the analysis was repeated when missing data were discarded (Motulsky, 1995). The former analysis (intention to treat) may make it harder to find significant differences, while the latter analysis (discarding missing data) may make it easier to find significant differences. Comparison of the demographic characteristics and other variables of the two groups at baseline were using the χ^2 test and t test according to whether the variables under consideration were categorical or continuous, respectively. The mean was used as an index of localization, and standard deviation as index of dispersion. Changes in NRS, Aberdeen LBP scale, spinal angular ROM in flexion-extension and reciprocal isokinetic trunk concentric flexor and extensor strength for the two groups immediately after the treatment series, at 1-month follow up and at 3-month follow up were assessed using a two-factor (group ×

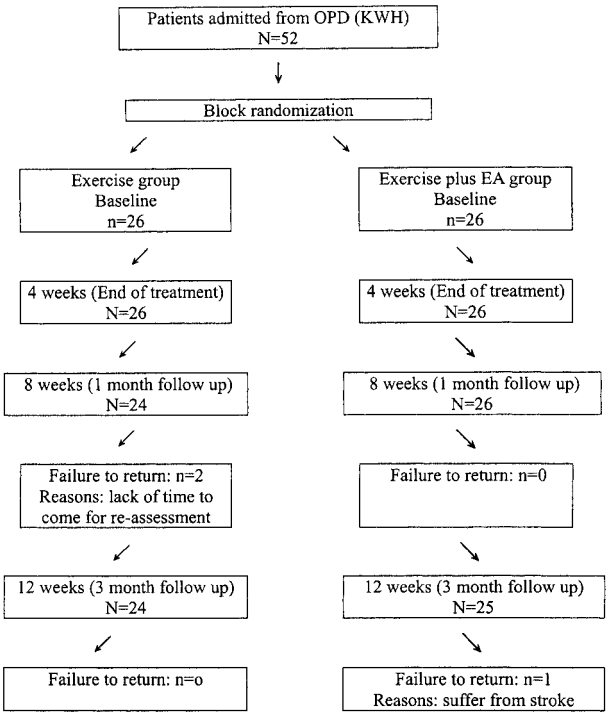

FIG. 2. Flow diagram describing the patients during the study period. OPD, outpatient department; EA, electro-acupuncture.

time of assessment) mixed repeated measures analysis of variance (R-ANOVA). Differences in the response over time between the two groups were indicated by a significant interaction. The level of significance was set at $p = 0.05$ in all comparisons. Analyses were performed using SPSS for Windows statistical software (version 10.0, SPSS, Inc., Chicago, IL).

RESULTS

Fifty-two (52) patients were entered to the study over a period of 12 months. None of them had undergone any back surgery before, and all subjects completed the treatment sessions. Three patients dropped out during the follow-up period. Two were in the back exercise group and defaulted at post-1–month follow-up because of lack of time to come for reassessment, and one patient in the back exercise plus EA group suffered from stroke before 3-month follow-up (Fig. 2).

Sociodemographic characteristics

Admission data for the patients are summarized in Table 2. There were no statistically significant differences between the two groups in terms of age, gender, body height, body weight, duration of symptoms, diagnosis, symptom radiation, and other treatment pro-

Table 2. Baseline Characteristic of the Subjects

Baseline characteristics	*Exercise group* (n = *26*)		*Exercise plus EA group* (n = *26*)		p *value (group difference)*
	n	%	n	%	
Age (mean; SD)	55.6; 10.4 years		50.4; 16.3 years		0.177[a]
Body height (mean; SD)	155.8; 7.0 cm		155.5; 7.8 cm		0.867[a]
Body weight (mean; SD)	59.1; 7.96 kg		61.72; 10.78 kg		0.324[a]
Gender					
Male	5	19.2%	4	15.4%	0.714[b]
Female	21	80.8%	22	84.6%	
Duration of symptoms					
6 month	4	15.4%	2	7.7%	0.665[b]
7–12 months	2	7.7%	5	19.2%	
13–18 months	2	7.7%	3	11.5%	
19–24 months	3	11.5%	2	7.7%	
> 25 months	15	57.7%	14	53.8%	
Presence of prolapsed intervertebral disc					
No	23	88%	26	100%	
Yes	3	12%	0	0%	0.074[b]
Radiation					
No	12	46.2%	12	46.2%	
Yes	14	53.8%	14	53.8%	1.00[b]
Analgesic consumption					
No	26	100%	25	96.2%	
Yes	0	0%	1	3.8%	0.313[b]
Exercise level					
No	10	26.9%	7	38.5%	
Yes	16	73.1%	19	61.5%	0.375[b]
Receive other forms of treatment					
No	20	76.9%	21	80.8%	
Yes	6	23.1%	5	19.2%	0.734[b]

[a]Independent T test.
[b]χ^2 test.
Radiation: complain of pain below the buttock level.
Analgesic consumption: no (not taken any analgesic); Yes (taken analgesic regularly or when necessary).
Exercise level: no (not perform exercise once per week); yes (perform exercise at least once per week).
Other forms of treatment: including *Tui Na*, massage, chiropactor, bone setter, using corset, or other treatment on the back.
EA, electro-acupuncture; SD, standard deviation.

grams prior to intervention. Blinded assessment showed that compliance with the back exercise program was equally good in both groups. No patient received any other type of therapy for back pain during the study period, and all patients tolerated EA well without adverse effects.

Outcomes

There were no significant differences between two groups with respect to analgesic consumption and exercise level before, post-treatment, post-1–month and 3-month follow up (Table 3). Although there were no statistically significant differences between the two groups at baseline, factors such as analgesic consumption and the presence of prolapsed intervertebral disc could confound the results, and outcomes were analyzed while controlling these two factors as covariates.

(1) *Pain*—On the NRS average pain score measure, interaction between group and time of analysis was significant ($p = 0.001$). Separate analysis of covariance (ANCOVA) was therefore performed to detect the difference between groups at any given time. The mean score was lower in the exercise plus EA group compared with the exercise group alone. There was a significant reduction in the average pain score between baseline and each of the follow-up assessments such as post-treatment ($p = 0.032$, 1-month follow-up ($p = 0.030$), and 3-month follow-up ($p = 0.005$) (Table 4).

For the worst pain score, interaction between group and time of analysis was significant ($p = 0.005$). Separate ANCOVA was performed to detect the difference between groups at any given time. The mean score was lower in the exercise plus EA group as compared with the exercise group alone. There was a significant reduction in the worst pain score at post-treatment ($p = 0.026$), to 1-month follow-up ($p = 0.018$) and 3-month follow-up ($p = 0.001$) (Table 4).

(2) *Disability*—On the Aberdeen LBP scale, interaction between group and time of analysis was significant ($p < 0.001$). Separate ANCOVA was therefore performed to examine the difference between groups at any given time. The mean score was lower in the exercise plus EA group compared to the exercise group alone. There was a significant reduction in the Aberdeen LBP scale post-treatment ($p = 0.002$), to 1-month follow-up ($p = 0.003$), and 3-month follow-up ($p = 0.001$) (Table 4).

(3) *Isokinetic muscle strength*—For the EPTBW 60° per second, the mean score was higher in the exercise plus EA group compared to exercise group alone at post-treatment to 1-month follow-up and 3-month follow-up, however, it was not significant ($p = 0.20$). It only demonstrated a significant difference between the various time periods

Table 3. Analgesic Consumption and Regular Exercise Performed Before, Post-Treatment, Post-One–Month Follow-Up and Post-Three–Months Follow-Up

		Exercise group n = *26*	*Exercise plus EA group* n = *26*	p *value (group difference)*
Analgesic consumption				
No/Yes	Pre	26/0	25/1	0.313
	Post	24/2	20/6	0.124
	Post-1–month	24/2	23/4	0.385
	Post-3–months	22/4	24/2	0.385
Exercise level				
No/Yes	Pre	10/16	7/19	0.375
	Post	8/18	3/23	0.090
	Post-1–month	7/19	3/23	0.159
	Post-3–months	7/19	3/23	0.159

χ^2 test used.
EA, electro-acupuncture.

Table 4. Changes in Pain, Disability, Spinal AROM, and Isokinetic Muscle Strength, Before, Post-Treatment, Post-One–Month Follow-Up and Post-Three–Month Follow-Up

Outcome variables	*Duration*	*Exercise group mean (SD)* n = *26*	*Exercise plus EA group mean (SD)* n = *26*	p *value*	*Power*	p *value (excluding missing data)*
NRS	Pre	5.88 (1.84)	6.38 (1.77)	0.323	69%	0.179
(average pain score	Post	5.12 (2.18)	3.81 (2.10)	0.032*		0.050*
(0–10)	Post-1–month	5.19 (2.47)	3.77 (2.12)	0.030*		0.077*
	Post-3–month	5.27 (2.31)	3.46 (2.18)	0.005*		0.018*
NRS	Pre	6.50 (1.56)	6.65 (1.77)	0.740	80%	0.516
(worst pain score)	Post	5.35 (2.04)	3.92 (2.43)	0.026*		0.049*
(0–10)	Post-1–month	5.42 (2.45)	3.85 (2.17)	0.018*		0.046*
	Post-3–month	5.65 (2.53)	3.46 (2.18)	0.001*		0.004*
Aberdeen LBP scale	Pre	32.49 (13.79)	35.32 (11.72)	0.429	89%	0.217
(0 = 100 points)	Post	30.82 (13.03)	20.02 (10.47)	0.002*		0.005*
	Post-1–month	32.48 (15.31)	20.36 (13.06)	0.003*		0.006*
	Post-3–month	25.82 (13.11)	19.86 (10.12)	0.001*		0.001*
Spinal AROM in	Pre	45.19 (16.02)	45.69 (22.81)	0.099	38%	0.140
flexion (degree)	Post	44.92 (15.14)	55.31 (24.08)			
	Post-1–month	43.46 (14.29)	50.42 (20.24)			
	Post-3–month	36.96 (14.31)	44.38 (13.90)			
Spinal AROM in	Pre	13.23 (7.62)	13.12 (7.40)	0.098	38%	0.066
extension (degree)	Post	13.31 (6.83)	16.42 (7.67)			
	Post-1–month	12.58 (6.88)	14.88 (5.72)			
	Post-3–month	9.77 (6.45)	12.77 (4.90)			
EPTBW 60 degree/	Pre	77.38 (50.20)	89.46 (55.28)	0.200	25%	0.263
sec (nm)	Post	89.62 (57.77)	119.27 (47.84)			
	Post-1–month	101.88 (80.06)	134.08 (84.28)			
	Post-3–month	108.46 (95.35)	143.85 (74.93)			
FPTBW 60 degree/	Pre	127.19 (79.16)	127.42 (63.28)	0.454	11%	0.663
sec (nm)	Post	125.73 (76.81)	156.54 (62.35)			
	Post-1–month	132.54 (78.67)	165.19 (67.96)			
	Post-3–month	183.19 (141.69)	212.58 (94.38)			
ETWBW 60 degree/	Pre	68.77 (65.44)	92.92 (61.16)	0.125	34%	0.194
sec (J)	Post	91.77 (73.47)	121.04 (47.29)			
	Post-1–month	92.85 (78.61)	129.42 (69.89)			
	Post-3–month	79.38 (79.15)	136.31 (185.53)			
FTWBW 60 degree/	Pre	117.23 (102.70)	138.42 (84.12)	0.204	25%	0.623
sec (J)	Post	113.27 (93.15)	161.27 (75.77)			
	Post-1–month	120.38 (101.26)	169.35 (83.49)			
	Post-3–month	145.08 (128.93)	179.54 (84.02)			

*$p < 0.05$.

AROM, angular range of motion; EA, electro-acupuncture; EPTBW, extensor peak-torque percent body weight; FPTBW, flexor peak torque percent body weight; NRS, numerical rating scale; LBP, low back pain.

within the subject group ($p = 0.000$) (Table 4).

For the FPTBW 60° per second, the mean score was higher in the exercise plus EA group compared to the exercise group alone at post-treatment to 1-month follow-up and 3-month follow-up. It only demonstrated a significant difference between the various time periods within the subject group ($p = 0.000$) but no significant difference was found between the two groups ($p = 0.454$) (Table 3).

For the ETWBW 60 degrees per second, the mean score was higher in the exercise plus EA group compared to exercise group alone at post-treatment to 1-month follow-up and 3-month follow-up. No significant differences within ($p = 0.119$) and between the two groups ($p = 0.125$) was found at any of the follow up periods (Table 4).

For the FTWBW 60 degrees per second, the mean score was higher in the exercise plus EA group compared to exercise group alone at post-treatment to 1-month and 3-

month follow-up. A significant difference between the various time periods was found within the subject group ($p = 0.008$) but no significant difference between the two groups was found ($p = 0.204$) (Table 4).

(4) *Spinal angular ROM*—For the angular ROM in flexion and extension, the mean of the exercise plus EA group was better than the exercise group alone at post-treatment to 1-month and 3-month follow-up. A significant difference between the various time periods within the subject group was seen (flexion: $p < 0.001$ and extension: $p < 0.001$) but no significant difference was found between the two groups (flexion: $p = 0.099$ and extension: $p = 0.098$) (Table 4). The analyses were repeated when all missing data were discarded. All conclusions were essentially identical between two groups, however, final conclusions were drawn from the intention-to-treat analysis.

DISCUSSION

The aim of this study is to determine if EA is an effective and safe treatment option that can reduce pain, decrease disability, and improve functional capacity of patients with chronic LBP. No adverse reaction to or complications arising from EA were found in this study. In this randomized trial, there was a significant reduction of pain and disability in the exercise plus EA group. While the results of spinal angular ROM and reciprocal isokinetic trunk measurement showed the mean changes to be superior in the exercise plus EA group at all time points, these differences did not reach statistical significance between the two groups.

These results support the growing body of literature that there is often little correlation among actual functional impairment (such as lumbar motion and muscle strength), disability and the self-assessment of pain (Hazard et al., 1994; Waddell, 1992). All of these physical measures are affected by patient's motivation, effort, and psychological state (Deyo, 1988). It has been concluded that these measures are poor at predicting long-term outcome, including return to full normal activity (Deyo, 1988). The results of these studies show that changes in these outcome measures were not always related to the changes in patient's ability to perform functional tasks. This demonstrates the importance of considering the multiplicity of factors that define the function and disability indexes of those suffering from chronic LBP. Because of this, many authors are now questioning the exclusive use of impairment measures to determine the outcome treatment (Deyo et al., 1994; Jette, 1995; Waddell, 1987). Therefore the impairment outcomes are only considered as secondary outcomes in the present study. The results of angular ROM in the current study were consistent with the finding of Edelist et al. (1976). One possible reason for lack of significant change in angular ROM may be because of the high baseline values found in this study, as most of the patients were able to reach below the knee in flexion and behind the thigh in extension. Another possible reason for the lack of significant change was the low power, ranging from 11% to 38% of these parameters (Table 4). A larger sample size may be needed to detect significant changes.

Different outcome measures probably measure different entities, and therefore to get a fuller picture of the intervention a combination of relevant outcome measures should be used (Delitto, 1994; Deyo et al., 1988; Jette, 1994). The current study takes this into account by using the Aberdeen LBP scale to evaluate the patient's progress after treatment. This disease-specific questionnaire is a simple clinical tool and contained questions adapted for Chinese subjects, giving a high level of reliability and validity (Leung et al., 1999). Use of a self-reported disease-specific questionnaire to assess a patient's level of function or disability in chronic LBP has been highly recommended (Paul and Christopher, 1997). As such, the Aberdeen LBP scale was used in combination with NRS as the primary outcome measure. Analysis after discarding the missing data or on the basis of an intention-to-treat analysis did not result in any significant changes in the results. Powers ranging from 69% to 89% were obtained for all of the primary outcome measures (Table 3), indicating a strong confidence in the short and medium-term pain relieving effect (NRS) and decrease in disability (Aberdeen LBP scale) in the exercise plus EA group com-

pared to back exercise alone. This outcome has been suggested by previous literature (Coan et al., 1980; Lehmann et al., 1986; MacDonald et al., 1983; Spitzer et al., 1987), but has been limited by unclear outcome measures and inconsistent effects.

The mechanism of EA might be explained by the findings that EA could accelerate the release of opioid peptides from the central nervous system (Han and Wang, 1992). An animal study also showed that repeated EA stimulation has cumulative therapeutic effect on chronic pain and suggested that EA analgesia and morphine analgesia share similar mechanism (Wang et al., 1992). Furthermore, Han et al. (1990) demonstrated that different frequencies of stimulation can facilitate differential release of different brain neuropeptides.

According to Traditional Chinese Medicine, chronic LBP is primarily because of deficiency in the kidney, and the treatment principle is therefore to reinforce the kidney and strengthen the bones. Unlike previous studies, which used a number of acupoints varying between subjects (Coan et al., 1980; Edelist et al., 1976; Gunn et al., 1980; Lehmann et al., 1986; MacDonald et al., 1983; Thomas et al., 1994), the current study only uses four acupoints: UB23 (*Shenshu*), UB25 (*Dachangshu*), UB40 (*Weizhong*), and SP 6 (*Sanyinjiao*), to reinforce the kidney *qi*, dredge the meridians, and activate the collateral (George et al., 1998). The use of these four acupoints resulted in reduced pain and disability, and as some patients have a fear of needle pain, avoiding excessive use of acupoints may be of benefit.

Limitations

There are a few limitations evident in this study. Concerns about subjects' long-term follow-up rate, meant that the follow-up period of the current study was 3 months after termination of the treatment series. Therefore, only the immediate and medium-term effects were demonstrated, but the long-term benefits of EA were not examined in this study.

An additional concern regards the lack of placebo or sham acupuncture control group in this clinical trial, in that there was no control for the additional time and attention in the EA group plus exercise group. It is not known whether the advantage found for this group is the result of the EA or to nonspecific treatment effects associated with these 12 sessions such as patient expectations or attention from the therapist. As such, it is impossible to prove whether EA was an important part of the treatment method or whether the improvement felt by the patients in the exercise plus EA group was due to the therapeutic setting and psychological phenomena (Lewith and Machin, 1983; Richardson and Vincent, 1986; Vincent et al., 1995). However, the interaction between patient and acupuncturist was minimized to exclude potential bias. No additional intervention was included, and conversation was limited to a short explanation about the procedure at each treatment session. Outcome evaluation was performed by a blinded assessor and self-reported questionnaire. While it has been argued that approximately 20%–30% improvement in short-term pain relief might be expected as a result of the placebo effect of acupuncture alone (Richardson et al., 1986), the present study showed approximately 40% to 45% improvement, indicating that EA is likely to demonstrate some analgesic effect apart from placebo. Nevertheless, further studies are required to add weight to the conclusion that EA has specific therapeutic effect beyond nonspecific placebo effects.

Both groups used a standardized back exercise program, and no studies have been performed to demonstrate the validity and significance of this program. Because the program involves both the flexion and extension exercise of the back, the therapist would ask patients for any increase in pain intensity after each exercise session to ensure that the exercise program was not resulting in increased pain and disability.

CONCLUSIONS

Despite the limitations of this clinical trial, the randomized clinical trial setting made it possible to control for cofounders such as age, gender, duration of pain, and selection bias. These controls, together with the comparably homogeneous patient group, blinded random-

ization procedure, standardized treatment and data collection procedure, low dropout rate (5.77%), blinded assessment, and data analysis using the intention-to-treat principle and discarding incomplete data sets all add to the reliability of this study. Positive effects of EA compared to back exercise group alone were demonstrated in a number of outcome measures including pain relief and functional capacities on disability level. This benefit was maintained at 3-months follow-up. It is concluded that EA has an additional value to standard back exercise, and may be an effective option in the treatment of pain and disability associated with chronic LBP. This study provides additional data on the potential role of EA in the treatment of chronic LBP.

Most of the previous studies in EA were lacking in methodological design and consequently the results produced are less than convincing. There is an urgent need for further well-designed clinical trials in this area. A well-designed, double-blinded, randomized study with larger sample size and a sham control group is recommended to examine both the short- and long-term effects of EA and to provide more definitive evidence of its effectiveness or otherwise in the management of chronic LBP.

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