

Research article critique

by Susan Kohut

Bilateral effect of 6 weeks unilateral acupuncture and electroacupuncture on ankle dorsiflexors muscle strength: A pilot study.

Authors: Zhou, S., Huang, L.-P., Liu, J., Yu, J.-H., Tian, Q., & Cao, L.-J.

Published: Archives of Physical Medicine and Rehabilitation

Volume 93, Issue 1, Pages 50-55, January 2012

Freely available at:

<http://download.journals.elsevierhealth.com/pdfs/journals/0003-9993/PIIS0003999311006927.pdf>

Introduction

The objective of the 2012 randomised controlled trial (Zhou et al, 2012) was to analyse how unilateral manual acupuncture at selected acupoints could alter ankle dorsiflexion strength bilaterally. They then compared the effect with electroacupuncture at the same acupoints and electroacupuncture at sham points.

This 2012 pilot study follows a trial published in 2007, the bilateral effect of unilateral electroacupuncture on muscle strength (Huang et al, 2007). In the Huang et al (2007), study electroacupuncture (40 Hz) was given unilaterally to acupoints ST36 & ST39 of 30 healthy males, three times weekly for four weeks. Dorsiflexion strength was analysed between the muscle strength pre-trial and after four weeks of acupuncture and between the two legs. A control group who did not receive acupuncture were also evaluated. The results demonstrated a statistically significant increase in the strength of both legs in the intervention group, the control group showed no significant change. Thus unilateral electroacupuncture improved ankle dorsiflexion strength in both legs

Zhou et al (2012) recruited 43 young healthy males (mean age 20.6 years) who were right foot dominant, had not had acupuncture or EMS before, not been involved in strength training for the six months before the study and who had no neurological or musculoskeletal disorders. They were randomly allocated, using a random number table, into one of four groups: Control group (Con), Manual acupuncture on acupoints (MAcu), Electroacupuncture on acupoints (EAcu) and electroacupuncture on sham points (ESham). The sham protocol involved needling into tibialis anterior at the 'top one third and lower one third of the muscle belly of tibialis anterior and 3cm lateral to the anterior crest of the tibia, thus avoiding any named TCM acupoints or meridians.

The acupoints used were ST36 & ST39. The participants in the experimental acupuncture groups received 15 to 30 minutes of acupuncture or electroacupuncture (40Hz, pulse width 1ms) on the right leg in each session, three sessions per week for six weeks. The only difference in the needling protocols was that in the sham group deqi was not obtained, instead only a level of pain. The deqi that was obtained was a 15 second twirling and lift-thrusting technique every five minutes.

All relevant ethics details (such as consent from all participants, ethics approval provided by the University Ethics committee which needs to be supplied for such a trial) were supplied. However later in the article there should have been a comment in regard to adverse events, even if there were none it should be recorded as such. Furthermore study details from Huang et al (2007) were erroneously referred to from Zhou et al (2012). It can be challenging to have to go back and check previous literature!

The primary outcome measure was the maximal strength in isometric ankle dorsiflexion of both legs. This was assessed before and after the experimental period, using a custom built device mounted with a force transducer. It is not noted whether the device or protocol undertook any pre-testing validation.

Pre intervention all groups demonstrated no significant differences between groups in maximal voluntary contraction (MVC). Following treatment repeated-measures analysis of variance (RMANOVA) identified significant and similar strength gains in the active (including ESham), treatment groups only. Post intervention the left leg strength was significantly stronger in all acupuncture groups; this was significantly higher than the no treatment control ($P < 0.5$). However it is noteworthy that the EA groups (real and sham) demonstrated significantly higher right leg MVC ($P < 0.5$), than the control group. Manual acupuncture did not show a significant difference in the right leg

Thus unilateral manual acupuncture and electroacupuncture at the acupoints and electroacupuncture at non-acupoints in the same muscle tissue can improve muscle strength in both limbs. Overall electroacupuncture provided greater reliability of strength gains than manual acupuncture alone.

Critical Analysis

PEDro critique of methodology

1. Eligibility criteria were specified (*Not counted in the final score*)
2. Subjects randomly allocated to groups
3. Allocation was concealed
4. Groups similar at baseline regarding the most important prognostic factors
5. Blinding of all subjects
6. Blinding of all therapists who administered therapy
7. Blinding of all assessors who measured at least one outcome
8. Measures of at least one key outcome were obtained from more than 85% of initially allocated subjects
9. All subjects for whom outcome measures were available received treatment or control as allocated, or if this was not the case, at least one outcome measure analysed using 'intention to treat' analysis
10. The results of between-group statistical comparisons are reported for at least one key outcome
11. The study provides both point measures and measures of variability for at least one key outcome

Pedro	1	2	3	4	5	6	7	8	9	10	11
Score	√	√	X	√	X	X	√	√	X	√	√

Score: 6/10 – a 'moderate' methodological score demonstrating 'moderate' rigour and trustworthiness in the RCT protocols. Furthermore randomisation was by a random number table, this can still open the randomisation to bias. However PEDro considers this item is as verifiable if random allocation is mentioned. Computer generated, off site randomisation is the 'gold standard'.

The article has not stated whether allocation to groups was concealed to those allocating participants to groups, hence did not receive a point for that item.

Note: Blinding is inherently difficult in acupuncture trials. If the therapists and patients are truly blinded then there could be some questions about the generalisability of the trial to everyday practice.

Item 9 did not receive a point because intention to treat analysis is not mentioned, and in the results section it notes that two participants data were invalid, but there is no description of how they 'made up for' their lack of outcome statistics. PEDro states "Analysis of data according to how subjects were treated (instead of according to how subjects should have been treated) may produce biases. It is probably important that, when the data are analysed, analysis is done as if each subject received the treatment or control condition as planned."

Cochrane critique of methodology

Score 2 points if absolutely meets the standard

Score 1 point if it is questionable if the standard was reached

Score 0 points if the standard has not been met.

Modified Cochrane Musculoskeletal Injuries Group Score Sheet

Was the assignment treatment adequately concealed prior to allocation?

- 2 = method did not allow disclosure of assignment
- 1 = small but possible chance of disclosure of assignment or unclear
- 0 = quasi-randomised or open list/tables

Were the outcomes of patients who withdrew well described and included in the analysis (intention to treat)?

- 2 = withdrawals well described and accounted for in analysis
- 1 = withdrawals described and analysis not possible; or not loss implied from the trials results (all participants included in analysis)
- 0 = no mention, inadequate mention, or obvious differences and no adjustment

Were the outcomes assessors blinded to treatment status?

- 2 = effective action taken to blind assessors
- 1 = small or moderate chances of unblinding of assessors
- 0 = not mentioned or not possible

Were the treatment and control group comparable at entry?

- 2 = good comparability of groups, or confounding factors adjusted for in analysis
- 1 = confounding small; mentioned but not adjusted for
- 0 = large potential for confounding, or not adjusted for

Were the subjects blinded to assignment status after allocation?

- 2 = effective action taken to blind subjects
- 1 = small or moderate chance of unblinding of subjects
- 0 = not possible, or not mentioned (unless double-blind), or possible but not done

Were the treatment providers blind to assignment status?

- 2 = effective action taken to blind treatment providers
- 1 = small or moderate chance of unblinding of treatment providers
- 0 = not possible, or not mentioned (unless double-blind), or possible but not done

Were care programmes, other than trial options, identical?

- 2 = care programmes clearly identical
- 1 = clear but trivial differences
- 0 = not mentioned or not clear and important differences in care programmes

Were the inclusion and exclusion criteria clearly defined?

- 2 = clearly defined
- 1 = inadequately defined
- 0 = not defined

Are the diagnostic criteria used relevant?

- 2 = clearly defined and relevant
- 1 = inadequately defined and validated
- 0 = not defined

Were the outcome measures used clearly defined? (by outcome measure)

- 2 = clearly defined
- 1 = inadequately defined
- 0 = not defined

Were diagnostic tests used in outcome assessment clinically useful? (by outcome)

- 2 = optimal
- 1 = adequate
- 0 = not defined, not adequate

Was the duration of surveillance clinically appropriate, with active and systematic follow-up? (by outcome measure)

- 2 = optimal (including active and systematic follow up)
- 1 = adequate (including active and systematic follow up)
- 0 = not defined, not adequate (and not active and systematic follow up)

Was there practical relevance of the intervention?

- (e.g. would ergonomists generally use this intervention for this condition)
- 2 = used often and easily performed
 - 1 = used rarely or difficult to perform
 - 0 = not used in the clinical setting

TOTAL

/26

Coch.	A	B	C	D	E	F	G	H	I	J	K	L	M
Score	1	1	2	2	0	0	2	2	2	1	0	0	2

15/26 - moderate methodological scoring. Boockock et al (2007) grade study scores between 10-19 as moderate methodologically.

STRICTA

1. Acupuncture rationale	1a) Style of acupuncture	TCM
	1b) Reasoning for treatment provided	No TCM, nor any other clinical reasoning provided. This is noted on p.53
	1c) Extent to which treatment was varied	Only in time as stated in 2f.
2. Details of needling	2a) Number of needle insertions per subject per session	Two in active treatment (not control) groups
	2b) Names of points used (uni/bilateral)	ST36 & ST39 unilateral in right leg, non acu-points described for sham
	2c) Depth of insertion	20-30mm into the muscle
	2d) Response sought	Deqi for active acupuncture (lift-thrust and twirling for 15 seconds every five minutes. Sham needling only sought a pain-like response
	2e) Needle stimulation (e.g. manual, electrical)	Control – no needling Manual acup. Group EA (40 Hz) real acup group EA (40 Hz) sham acup group
	2f) Needle retention time	15 minutes in first week 20 minutes in week two 30 minutes in weeks three to six
	2g) Needle type (diameter, length, and	Needle diameter – 0.30 gauge and

	manufacturer or material)	50mm long only information provided
3. Treatment regimen	3a) Number of treatment sessions	Three sessions per week for six weeks
	3b) Frequency and duration of treatment sessions	See 3a. for details provided
4. Other components of treatment	4a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice)	No other interventions provided. Control group attended for the same number of sessions but only participated in warm up and cool down activities
	4b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients	Only treatment criteria has been provided. Instructions to practitioners and information/explanations has not been provided
5. Practitioner background	5) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)	TCM practitioner with a Bachelor's degree in TCM and 10 years' experience
6. Control or comparator interventions	6a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice	No rationale for the selection of the sham points is provided
	6b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above.	Precise description of sham needling sites and no treatment control group.

In summary – methodologically: both PEDro and Cochrane critical appraisal tools demonstrate that the published trial demonstrated moderate methodological rigour. STRICTA – which tells us more about the ‘doing’ of the trial is not usually scored. However it has been used in some critiques to compare STRICTA findings to other trials. This is to demonstrate replicability and provides a dimension of trustworthiness. Most STRICTA points have been answered, but more detail would have enhanced the study dissemination, such as rationale and clinical reasoning for point selection, and use of EA frequency.

Discussion

This article, and its predecessor, demonstrates something that we as physiotherapists providing acupuncture have known for some time – acupuncture does enhance motor skills. This enables movement/exercises to be done more effectively. What is exciting is that over time an alteration in strength can be elicited. What we do not know is how much long term carry-over could this provide, such as enhanced motor outputs for athletes (given that the populations studied were young males who were not engaged in sporting activities). Furthermore could this enable improvements in motor control in upper or lower motor neuron neurological conditions such as nerve injury or stroke? Further trials are required! Anecdotally I have used low frequency (2-4 Hz), high intensity EA to improve muscle contraction in patients when FES was too uncomfortable or did not elicit a particularly good contraction. The EA carryover then allowed them to progress onto FES use. However I cannot remember when I last gave a patient 18 treatments over a six week period! Or at 40Hz!

The ability to increase strength bilaterally from unilateral stimulation provides further evidence to support bilateral needling or needling contralaterally, such as when needling the ipsilateral side may be detrimental, such as in acute CRPS (Longbottom, 2005). Of the ascending nociceptive tracts activated by acupuncture, many of the axons of the spinoreticular tract are known not to cross the midline (Kandel, Schwartz & Jessell, 1991), hence enabling

stimulation of higher centres bilaterally. Nociceptive acupuncture sensory stimulation processed in the dorsal horn laminae ascend largely through the spinoreticular tract (Bowsher, 1998).

What does concern me in regard to this trial is the use of control/sham needling into an area which had the same segmental myotomal innervation. I concur with Langevin et al, (2011), MacPherson & Hammerschlag (2012), and Madsen, Gøtzsche & Hróbjartsson (2009), who have considered whether acu-point specificity is inherent to acupuncture effects or whether innervation has a role to play in the acupuncture effect. In this trial all acupuncture needling was performed to the anterior lower leg, assumedly to tibialis anterior muscle and the area innervated by the deep peroneal nerve. Thus the myotomal and dermatomal innervation of all needling was to nerve root L4/L5. The article does state that all needling was done into the muscle, using a 0.3mm gauge needle and to a depth of 20-30mm (Zhou et al, 2012).

Chan (2002) notes that segmental acupuncture causes a change to the segmentally related α -motor neuron excitability (which can last up to 30 minutes). Furthermore he notes that intensity of deqi does not appear to have a correlation with α -motor neuron excitability. Chan (2002) and Bradnam (2003/2011) state that despite the analgesic effect of acupuncture being well known, there is scant understanding of the acupuncture mechanisms underlying motor changes. I suggest that it would have been prudent to have sham needled in an area outside of the L4/5 segments for a better control. I also have doubts that a the control group were not subconsciously biased into a greater level of activity, given that they attended eighteen warm up and cool down sessions.

Other notions are that there also could have been more differences between the 2007 and 2012 trials, besides adding a sham group, treating over a longer time period and using a different outcome method. Perhaps an active exercise group, without acupuncture, in a group of healthy participants would have been a more telling control for the real world. Cost effectiveness is a by-word in trials in these times of less funding for healthcare, so acupuncture should not supercede exercise. Much more detail and real world application would have enhanced the study's applicability and analysis.

The main take home message is motor changes can occur in an area that is segmentally related (or the muscle itself), when acupuncture needled. Electroacupuncture at TCM acu-point's and non-acupoints both showed significant changes compared to no acupuncture. Any acupuncture caused significant ankle dorsiflexion strength compared to no acupuncture - but unfortunately was not compared to active exercise! However this provides food for thought next time one is trying to elicit more specific or stronger/any muscle activity when rehabilitating a patient.

References

Bowsher, D. (1998). Mechanisms of acupuncture. In Filshie, J. & White, A. (Eds). *Medical Acupuncture. A western scientific approach*. Edinburgh, U.K.: Churchill Livingstone.

Boocock, M.G., McNair, P.J., Larmer, P.J., Armstrong, B., Collier, J., Simmonds, M., & Garrett, N. (2007). Interventions for the prevention and management of neck/upper extremity musculoskeletal conditions: a systematic review. *Occupational and Environmental Medicine*, 64, 291-303. doi:10.1136/oem.2005.025593

Chan, A. K.S. (2002). The effect of acupuncture on alpha-motoneuron excitability (Masters Thesis, Auckland University of Technology, Auckland, New Zealand). Retrieved from <http://hdl.handle.net/10292/173>

Huang, L.P., Zhou, S., Lu, Z., Tian, Q., Li, X., Cao, L.J., Yu, J.H. & Wang, H. (2007) Bilateral effect of unilateral electroacupuncture on muscle strength. *Journal of Alternative and Complementary Medicine*, 13(5), 539-546. Retrieved from <http://www.liebertonline.com>

Kandel, E. R., Schwartz, J.H. & Jessell, T.M. 1991. *Principles of neural science*. NY, USA: McGraw Hill C

Langevin, H.M., Wayne, P.M., MacPherson, H., Schnyer, R., Milley, R.M., Napadow, V., ... Hammerschlag, R. (2011). Paradoxes in Acupuncture Research: Strategies for Moving Forward. *Evidence-Based Complementary and Alternative Medicine*, 2011 (2011). doi:10.1155/2011/180805

Longbottom, J. (2005). Not so simple pain. The complexity of chronic pain management. *The Journal of Chinese Medicine* 79, 53-59. Retrieved from <http://www.pacificcollege.edu/index.php>

MacPherson, H. & Hammerschlag, R. (2012). Acupuncture and the emerging evidence base: contrived controversy and rational debate. *Journal of Acupuncture and Meridian Studies*, 5(4):141-7. doi: 10.1016/j.jams.2012.05.001.

Madsen, M.V., Gøtzsche, P.C., & Hróbjartsson, A. (2009). Acupuncture treatment for pain: systematic review of randomised clinical trials with acupuncture, placebo acupuncture, and no acupuncture groups. *British Medical Journal*; 338:a3115. doi: 10.1136/bmj.a3115

Zhou, S., Huang, L.-P., Liu, J., Yu, J.-H., Tian, Q. & Cao, L.-J. (2012), 'Bilateral effects of 6 weeks' unilateral acupuncture and electroacupuncture on ankle dorsiflexors muscle strength: a pilot study. *Archives of Physical Medicine and Rehabilitation*, 93,(1), 50-55. doi:10.1016/j.apmr.2011.08.010

Susan Kohut MHSC (Hons), Dip Phty, Reg Phty Acu
PAANZ Tutor
