

## Difficulty of Clinical Trials of Acupuncture

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We had retrieved and analyzed clinical evidence of acupuncture for low back pain using medical literature database (Medline and 医中誌) at 1995. There were 12 literatures in Japanese language journal and 13 literatures in English journal which had control group. Results from trials, which used sham acupuncture as placebo control, failed to prove specific effect of acupuncture. Evidence from the other types of trials, which compared standard care plus acupuncture with standard care alone and compared acupuncture with no treatment control, suggested that acupuncture was effective.

Systematic reviews (SRs) on acupuncture for LBP were published in 1998 (Ernst) and 1999 (Tulder). In the former SR, data was synthesized, but meta-analysis failed to show specific effect of acupuncture with sham acupuncture control. The latter SR reported strong heterogeneity among the trials. Therefore, meta-analysis was avoided and qualitative assessments were performed. And data did not show advantage over any types of control. Authors of both SRs regarded that quality of trials were generally low.

Quality of clinical evaluation of acupuncture in early stage was regarded as poor on study design. Their attempt to introduce research methodologies into acupuncture study was not easy. Origin of research methodology is clinical pharmacology and that is characterized by nature of drug therapy. Needless to say, acupuncture therapy is one of complex intervention and appropriate parameter for prescription of acupuncture procedure has not yet been clearly defined.

Methodological issue focused on appropriate interventions on acupuncture trial had been addressed to probe specific effect of acupuncture.

Thereafter, at 2005, two SRs Manheimer (2005) and Furlan (2005), on acupuncture treatment for LBP were published and their results succeed to prove specific effect of acupuncture. We had believed that progress in appropriate setting of intervention make reduce type II error and we believed that we might free from the difficulty of specific effect of acupuncture.

Regrettably, evidence is not proving the specific effect of acupuncture on low back pain at present. What should we do in order to break the bottleneck?

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