Editorial

A new addition to evidence lists for clinical efficacies of acupuncture treatment: a comment on the currently published paper in JAMA, "Effect of Electroacupuncture on Urinary Leakage Among Women With Stress Urinary Incontinence: A Randomized Clinical Trial"

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Stress urinary incontinence (SUI) is a prevalent condition which affects considerable impact on quality of life in old women (1). If lifestyle interventions including pelvic floor muscle training, body-weight reduction, drink-intake controlling, scheduled-voiding and constipation management are not effective, surgical treatments such as incontinence pessaries, Burch colposuspension, autologous fascial slings, midurethral slings and vaginal mash are recommended for this population, but the evidence on the effectiveness and safety of these interventions is not currently inconclusive (2). As a non-surgical treatment option for SUI, acupuncture is one of the alternatives for this condition, but evidence on the benefit and harm of acupuncture has not been established clearly, either. From a Cochrane review, the evidence on the effect of acupuncture for SUI is found to be uncertain due to scanty of clinical trials which included only small number of patients and showed methodological limitations including problems in random sequence generation, blinding of participants and invalid outcome assessments (3). In this aspect, current report on the clinical trial about the effect of acupuncture for women with SUI is very valuable for establishing rigorous clinical evidence of acupuncture (4).

A multicenter randomized controlled trial testing the efficacy and safety of electroacupuncture for women with SUI was conducted by 12 hospitals in China. 504 SUI women (average aged 55.3, SD 8.4 years) diagnosed with their clinical symptoms and 1-hour pad tests were randomly assigned to either 18-session of electroacupuncture on bilateral BL33 and BL35 or sham electroacupuncture on non-acupuncture points, and subjective and objective standardized outcomes for SUI were assessed up to 30 weeks. The result showed that 6-week of electroacupuncture was more effective in reducing urine leakage than sham electroacupuncture (adjusted mean difference 7.4 g, 95% CI: 4.89 to 10). In addition to this, the episodes of urinary incontinence during 72 hours in electroacupuncture group were reduced significantly compared to sham electroacupuncture group (1.0 episode per week less between week 1 and 6). The results of International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), which is a standardized self-reporting instrument for the quality of life in the patients with urinary incontinence suggested that meaningful improvement was achieved in the electroacupuncture group after 18-sesssion of treatments. Even more encouraging fact is that these significant differences in the subjective and objective outcomes between groups immediately after 6 weeks of acupuncture were maintained up to 30 weeks. About the adverse events (AEs),

there was no serious AE related to the interventions, and only minor AEs were reported in both groups.

This study has strong points which overcome limitations of previous evidence. First is the methodological rigor. To reduce bias, several things need to be considered when designing clinical trials: random sequence needs to be generated in an appropriate manner. Allocation results should be concealed not to be assessable and predictable. Participant, study personnel and outcome assessor blinding is critical for the prevention of performance bias. Drop-out needs to be prevented if avoidable and appropriate methods should be used for statistical analysis as drop-outs cannot affect true effect estimates. All the outcomes intended should be reported although there is no significant difference between groups to eliminate publication bias (5). In these senses, this is assessed as a low risk of bias study in most of these domains. Second, enough sample size which had been calculated using a previous study was recruited in this study. It has been criticized that most acupuncture studies are under-powered which is the main reason for the negative results of acupuncture trials (6). This study recruited 504 SUI patients, which prevented from over-estimation of therapeutic effect affected by small sample size of the study. Third, external validity could be achieved through multi-hospital involvements for this study. Multicenter trial has strong points in speedy recruitment of participants for clinical studies. But more important merit is that it can ensure external validity of the intervention. All these factors contributed to making the evidence derived from this study more confident and reliable.

This study left a little to be desired in several points as well. About the sham intervention, more detailed information would have been helpful for future researchers. The authors described that pragmatic placebo needles similar to the Streitberger needles were used in this study. There are two issues here: one is the sham intervention itself, and the other is the blinding of the participants. Streitberger needles have several delicate components, so figures or detailed explanations on each part of the sham acupuncture needle should have been described fully. The authors declared that they evaluated successfulness of blinding for only small number of patients in 2 hospitals, but it cannot ensure whether most patients in sham group felt that they were treated with real acupuncture or not.

About the method for ensuring internal validity of the acupuncture treatments, the authors handled study sites as a random variable which was adjusted through the statistical analysis. I wonder whether there are any differences in effects estimates which can be explained by the practitioner's experiences and proficiency in the different hospitals. From the protocol of this study, I found that only description on the practitioner's information was "TCM practitioners with a clinical acupuncture experience ≥2 years". Were there any efforts to ensure the practitioner's level constant across the participating centers such as educational programs or checkup process for practitioners?

About the tolerability of heterogeneous acupuncture treatment methods for SUI patients, electroacupuncture on BL33 and BL35 is a well-established therapeutic acupuncture prescription for SUI, but there could be alternative points or stimulation methods for this condition. This might be a new question left for future clinical trials.

Acupuncture is a common intervention practiced in many countries, but there is not much research that identified the differences between countries. In this sense, the final word for this editorial is a suggestion for multi-national clinical study on acupuncture for this condition. There could be ethnic or environmental differences in the therapeutic effect of acupuncture. These kinds of research activities will make fruits of more abundant list of clinical evidence of acupuncture in future.

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Footnote

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appropriately investigated and resolved.

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