

Reevaluating Acupuncture Research Methods

In this issue of the *Archives*, Suzuki et al¹ examine an important and relevant area of acupuncture research. Previously, Jobst et al² identified that acupuncture may be of value in chronic obstructive pulmonary disease (COPD), but subsequent acupuncture research has focused largely on its use in chronic pain.^{3,4} We have a limited range of conventional interventions for COPD, and the addition of safe, effective treatments that significantly improve quality of life is of great importance for this chronic, disabling, and frequently terminal condition.⁵

The article by Suzuki et al¹ is thoughtful and methodologically rigorous, indicating that acupuncture creates significant improvement for patients with COPD across a range of patient-centered and physiologic outcome measures over and above standard care. The model validity of the intervention is based on a standardized acupuncture protocol derived from a traditional Chinese medical (TCM) approach in which acupuncture points are used based on acupuncture theory. The patients appeared to be adequately masked, and the clinical, respiratory, and quality-of-life outcomes are well validated. One of the study's most interesting aspects is the embedded mechanistic explanation, which clearly suggests that improved respiratory muscle function through decreasing respiratory muscle tone results in recovery of respiratory muscle strength and muscle function. The relaxation of accessory respiratory muscles results in improved inspiratory and expiratory mouth pressures in association with increased movement in the rib cage. This improved respiratory function was associated with improvements in symptoms and quality of life. In addition, individual nutritional status improvements are reported. The effect size reported is large and, if replicated, indicates acupuncture is an important and effective non-pharmacologic modality for COPD management.

Where does this study lead us? The authors note that acupuncture must be used in addition to conventional care, and although this is undoubtedly correct, it may have significant economic implications. Evaluating traditional interventions, such as acupuncture, that are widely available has many implications, including the fact that best practice and dose response have rarely been evaluated scientifically as would be the case for a new pharmaceutical agent.⁶ Acupuncturists are often at odds about best practice, and within the context of chronic long-term conditions, such as COPD, addressing what is best practice and how frequently to provide treatment will be key to health care decision makers when evaluating the cost benefit of acupuncture.

The authors have used a standardized TCM-based acupuncture prescription, which improves our capacity to reproduce these findings. However, the very principles of TCM are based on an individualized prescription, and

many acupuncturists would argue that this is an essential component of good acupuncture practice. The use of TCM is an ongoing tension within acupuncture research and practice that has yet to be resolved with good clinical science embedded into pragmatic studies.

Within the context of COPD, this study suggests a clear difference between real and placebo acupuncture and points to rational mechanisms through which it may operate, which should be further explored. Most research within the field of acupuncture has been performed for pain, which has generated considerable debate about whether techniques such as the Park and Streitberger needle are true placebos or simply a poor form of acupuncture.⁷ Studies^{3,4} comparing acupuncture with standard conventional treatment have revealed that placebo needling for pain creates some significant clinical benefits, but in most conditions, real acupuncture is superior to placebo needling. The differences between real and sham or placebo acupuncture for nausea⁸ are much more significant, with real acupuncture showing clear benefits over placebo acupuncture. This finding suggests that the conceptual hypotheses developed approximately 20 years ago on how to design acupuncture trials based on our mechanistic understanding of the therapy may have some validity.⁹ The underlying mechanisms involved in the treatment of pain may invoke point-specific and non-point-specific (placebolike and endorphin-mediated) mechanisms, thus confounding the concept of a true acupuncture placebo when using either sham or nonclinically indicated acupuncture points as controls. When treating conditions such as COPD or nausea, it may well be that the mechanisms involved demand clear point specificity because the underlying mechanisms are specific and therefore the differences between real and sham acupuncture treatments are likely to be more clinically significant. This finding suggests that there are a number of mechanisms through which acupuncture may be exerting its clinical effectiveness and that understanding these specific underlying mechanisms may significantly affect the consequent clinical trial design. Suzuki et al¹ have reopened an important debate. They have reignited the issues around use of acupuncture in chronic respiratory disease and have raised some central methodologic points about study design and health economics. How should we design acupuncture studies when we are frequently unaware of the underlying physiologic and biochemical mechanisms? How do we design appropriate placebo and control interventions? What is a reasonable dose of acupuncture? What is best acupuncture practice? How much does acupuncture cost? To understand how we can integrate acupuncture effectively and on an evidence base into our health care provision models, we need to consider moving away from its use in chronic pain toward its more traditional and historically embed-

ded application in a range of chronic long-term medical conditions.

This study points to an important potential role for acupuncture in COPD management. These findings demand larger but equally methodologically rigorous confirmatory studies if we are to consider integrating this approach into our management strategy.

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