

EFFECTS OF ACUPUNCTURE IN REDUCING ATTRITION AND MORTALITY IN HIV-INFECTED MEN WITH PERIPHERAL NEUROPATHY

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Objective: A clinical trial reported in JAMA (Shay et al, 1998), involving acupuncture and amitriptyline in HIV-infected patients, concluded that there was no effect for either acupuncture or amitriptyline on neuropathic pain. However, a recent reassessment of this study showed that there were really three different and independent clinical trials, each with a different research design, which had been combined into a single database and consequently analyzed with a relatively insensitive statistics. When only the first substudy, factorially crossed design involving acupuncture and amitriptyline, was reanalyzed by itself using more powerful statistics, it was found that acupuncture and amitriptyline both worked independently to reduce pain, but also that acupuncture worked best in the absence of amitriptyline, and that there may have been adverse events associated with the combination of the two treatments. The present study reports the reanalysis of the second of the original independent studies involving only acupuncture and sham acupuncture, to determine whether the results confirm acupuncture-related findings from the first substudy.

Participants: Subjects were 114 HIV-infected men with pain associated with peripheral neuropathy in the early 1990s, when antiretroviral drug cocktails were just beginning to be available in experimental form.

Research Design: The second of the independent studies in the original report by Shay et al involved a single factor with two levels: a 14-week standardized acupuncture regimen and its control (off-point sham acupuncture). In addition, physical functioning at baseline (high or low, based on the Karnofsky scale), was factorially crossed with the acupuncture factor in our analyses. Primary data were reanalyzed using repeated-measures ANCOVA in an intention-to-treat procedure, and categorical data were analyzed by the Pearson chi-square test.

Outcome Measure: Pain intensity, pain relief, mortality, and attrition.

Results: Whereas the results were inconclusive for the pain measures, acupuncture had a strong and positive effect on attrition and mortality. These results were most pronounced among patients with poorest physical functioning at the beginning of the study. Overall, acupuncture was associated with lower attrition rate (27.6% vs. 44.6%, $P = .058$), and a zero mortality rate (0% vs. 12.5%, $P = .047$). This protective effect of acupuncture was visible primarily in subjects in poorer health (0% vs. 23.8%, $P = .047$).

Conclusions: Acupuncture was clearly effective in reducing attrition and mortality in this sample, especially when health status was taken into account, but results for pain relief were mixed. These results add further evidence that the use of the most sensitive statistics available increases the chance of detecting actual effects due to acupuncture (and other treatments as well). Moreover, these results replicated most of the findings that did not involve the presence of amitriptyline from the initial independent study in this research project. The combined results of these two studies strongly support the importance of recognizing that interactions involving acupuncture and other treatments, may positively as well as negatively modify main effect results in clinical trials, and thus must be recognized and systematically explored. Findings are discussed in terms of their implications for moving toward a whole-systems approach to biomedical research.

Key words: Acupuncture, HIV, neuropathic pain, mortality, attrition, adverse event, statistics

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INTRODUCTION

Acupuncture has been shown in a number of studies to be effective for reducing pain involved in a variety of different medical conditions, a fact that has been acknowledged by the National Institutes of Health.¹ Despite the abundance of posi-

tive findings supporting the relationship between acupuncture and reduced pain, some studies do not show a clear-cut benefit to acupuncture, showing either weak results or no effect.¹⁻³ Vickers⁴ recently demonstrated that the weak findings in four acupuncture pain studies⁵⁻⁸ were due in part to inadequate statistical analysis. However, when a more sensitive statistical method (analysis of covariance, ANCOVA) was applied to the raw data from these four studies, stronger results emerged in support of the effectiveness of acupuncture.

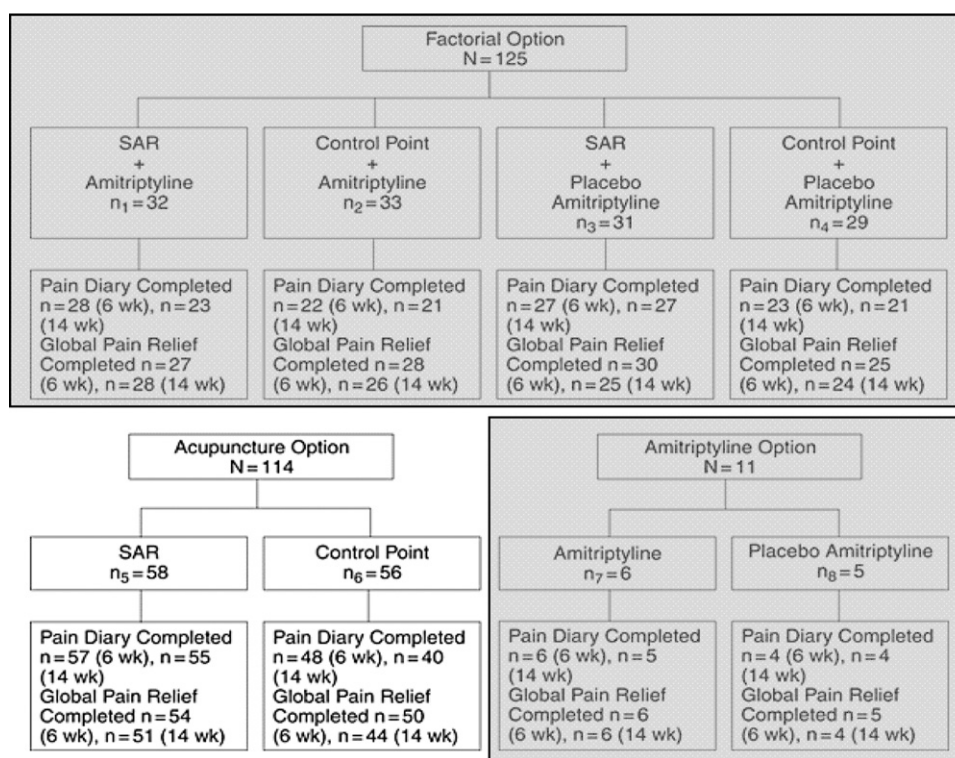
Another study of acupuncture for pain, involving peripheral neuropathy in patients with advanced HIV disease, concluded that neither acupuncture nor an active comparison treatment, amitriptyline, had any effect on pain intensity.³ This study was a

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The standardized acupuncture regimen (SAR) vs control points (CPs) compares n₁ + n₃ + n₅ with n₂ + n₄ + n₆. The amitriptyline vs placebo compares n₁ + n₂ + n₇ with n₃ + n₄ + n₈.

Figure 1. Flow chart plus figure legend for the three studies comprising the original Shlay et al study reported in *JAMA*, 1998. The data analyzed in this paper are from the “Acupuncture Option” substudy, not darkened in the figure. (Copyright © 1998, American Medical Association. All rights reserved)

large, multisite clinical trial that is unique in that it involved severely ill patients with outcomes that include pain management as well as attrition and an unusually high death rate, and is unlikely to ever be replicated due to prohibitive costs and the nature of the illness: advanced HIV disease at a time when adequate treatment was not yet available.

As shown in Figure 1, reprinted from Shlay et al, that study actually consisted of three independent studies or “options.” The Factorial Option was their originally planned study: an elegant 2 × 2 factorially crossed design involving acupuncture and amitriptyline and their corresponding control groups, sham acupuncture, and placebo pill. Options 2 and 3 were added two years after the study began, and involved one-way designs involving only acupuncture and its sham condition (in Option 2), or amitriptyline and its placebo pill condition (in Option 3).

Because these latter two designs were not compatible with the 2 × 2 design of the “Factorial” Option, the originally planned statistical analyses were substantially modified to a point where it was no longer possible to directly compare amitriptyline to acupuncture. The statistical design that was actually used is presented in the legend of their Figure (2), reproduced here as Figure 1, ended up being much less sensitive than their originally planned 2 × 2 factorial analysis of variance (ANOVA).³ Their modified statistical approach assumed that there was no interac-

tion between acupuncture and amitriptyline, because, as shown in the legend of Figure 1, components of each factor were included in the other factor. In other words, the two factors in the 2 × 2 design, acupuncture and amitriptyline, were not independent of each other, thereby making direct comparisons between acupuncture and amitriptyline impossible. For all these reasons, it seemed likely that the results reported by Shlay et al substantially underestimated the true effects.

To examine this possibility, Shiflett and Schwartz⁹ reanalyzed the original raw data from that study using only the patients enrolled in their original 2 × 2 factorial design option, to determine whether the increased statistical power achieved by using this approach, despite a reduced sample size, would yield more positive results for either acupuncture or amitriptyline. In contrast to the findings reported by Shlay et al, Shiflett and Schwartz found that both acupuncture and amitriptyline independently aided in pain relief, and perhaps more importantly, acupuncture was associated with fewer deaths and a much lower attrition rate than in any other condition, *except* in the presence of amitriptyline, where there was a significant *increase* in the risk of death and attrition. These effects were most pronounced in patients in poorer health at baseline.

The purpose of the present study was to reanalyze the data from the “Acupuncture” Option (Option 2, see Figure 1), which

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