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Pregabalin Is Similar to Placebo for HIV-Related Neuropathy

Neuropathic pain improved substantially with both pregabalin and placebo.

Some of the characteristic sequelae of late-stage HIV infection have almost disappeared from the average clinician's office. However, peripheral neuropathy persists and can be extremely difficult to treat.

In a manufacturer-supported multicenter blinded study, 302 HIV-positive patients with neurologist-confirmed peripheral neuropathy were randomized to daily placebo or pregabalin (≤ 600 mg) for 14 weeks. The average study participant had been HIV-positive (CD4 count, ~ 450 cells/mm³; viral load, $< 20,000$ copies/mL) for more than a decade and had complained of neuropathic symptoms for more than half that time. Stable regimens of background pain medication were allowed throughout the study.

During the first 2 weeks, the pregabalin group experienced a significantly greater diminution in pain as measured on a standard scale, but, by 14 weeks, the difference was no longer significant. Secondary outcomes (such as sleep interference) also were not different at 14 weeks. One subgroup of patients — those with the greatest sensitivity to pinprick — had a highly significant response to pregabalin. Treatment-limiting side effects of the drug were rare and included dizziness, somnolence, and confusion.

Interestingly, the analgesic effect of pregabalin in this study was comparable to that achieved in similar studies among diabetic patients and others, in which the drug was significantly more effective than placebo. However, the placebo response among these HIV-positive patients was so large that the drug's effect became nonsignificant.

Comment: The authors summarize the situation well: Control of pain caused by HIV-related peripheral neuropathy "is a large unmet need." Clearly, pregabalin is not a magic bullet, but it could be helpful in a subgroup of patients. Notably, this study is not the first in which a treatment for HIV-related peripheral neuropathy has elicited an unusually high placebo response. The reasons behind that phenomenon would be extremely interesting to pursue — might HIV-positive individuals have greater faith in the power of medication than do others? On a research level, the authors suggest counteracting this phenomenon by devising studies that minimize placebo effect as much as possible.

— [Abigail Zuger, MD](#)

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