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Transdermal clonidine compared to placebo in painful diabetic neuropathy using a two-stage 'enriched enrollment' design.

Byas-Smith MG[1], Max MB, Muir J, Kingman A.

Author information

Abstract

Because a variety of mechanisms may generate pain in neuropathic pain syndromes, conventional clinical trial methods may fail to identify some potentially useful drugs; a drug affecting just a single mechanism may work in too few patients to yield a statistically significant result for the trial. To test a previous clinical observation that approximately one-quarter of patients with painful diabetic neuropathy appear responsive to clonidine, we conducted a formal clinical trial of transdermal clonidine in painful diabetic neuropathy patients using a 2-stage enriched enrollment design. In the first stage (study 1), 41 patients with painful diabetic neuropathy completed a randomized, 3-period crossover comparison of transdermal clonidine (titrated from 0.1 to 0.3 mg/day) to placebo patches. Twelve apparent responders from study I were entered into the 'enriched enrollment' second stage (study II), consisting of an additional 4 double-blind, randomized, 1-week treatment periods with transdermal clonidine and placebo. Study I showed that in the overall group of 41 patients, pain intensity differed little during clonidine and placebo treatment. In study II, however, the 12 apparent responders from study I had 20% less pain with clonidine than placebo (95% confidence interval (CI): 4-35% pain reduction; P = 0.015), confirming that their pain was responsive to clonidine. None of the 3 consistent clonidine responders who were tested with the alpha-adrenergic blocker phentolamine had relief of pain, suggesting that clonidine's pain relief is not mediated by a decrease in sympathetic outflow. A post-hoc analysis of many variables suggested that patients who described their pain as sharp and shooting may have a greater likelihood of responding to clonidine.(ABSTRACT TRUNCATED AT 250 WORDS).

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