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Pentoxifylline and Diabetic Neuropathy

I recently reviewed the article by Cohen et al. (1) whereby the authors conclude that pentoxifylline does not differ from placebo in its effects on painful diabetic neuropathy. Although the design of the trial appears superficially sound, it suffers from several significant problems.

First, the sample size was too small. The study compared 12 patients on active pentoxifylline to 9 on placebo. At our institution, we performed a sample size calculation for a trial of pentoxifylline for diabetic neuropathy. That calculation suggested that 120 subjects (60 active, 60 placebo) are needed to determine the efficacy of pentoxifylline for this condition.

Second, the authors of this study omitted any placebo run-in period. In all chronic pain studies, there is a tremendous early placebo effect. This has also been true of claudication trials on pentoxifylline. Thus, any useful evaluation of pentoxifylline for painful diabetic neuropathy must include a placebo run-in of at least 6 wk.

Third, as outcome variables, the authors evaluated only global pain scores. Symptoms (pain, paresthesia, numbness) are not dissected out. No neurological, physical, or electrophysiological correlates are reported.

In summary, the trial was insufficient in scope for its authors to make any definitive conclusions about the usefullness of pentoxifylline for diabetic neuropathy.

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Reply

Our article described short-term trials of clonidine and pentoxifylline in the therapy of painful diabetic peripheral neuropathy (1). The use of pentoxifylline had been prompted by our own anecdotal observations on 8 patients given the drug to observe its effects on proteinuria; 6 patients noted an improvement in neuropathic symptoms within weeks of starting pentoxifylline. Unfortunately, a 12-wk double-blind trial involving 21 patients (12 active drug, 9 placebo) failed to confirm this finding. Although there was a significant decrease in pain, the response was no better than the placebo effect. Also, there was no effect on separate symptoms such as numbness and burning and no change in nerve conduction tests.

As Dr. Sainati states, it is certainly possible that a significant effect may be found in a larger cohort of patients treated for a longer time. If neuronal ischemia is a contributor to diabetic neuropathy, then patients with significant peripheral vascular disease may be more likely to benefit, as we suggested in our article. However, there was no dramatic short-term effect of pentoxifylline on neuropathic pain in patients with little or no peripheral vascular disease.

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Insulin Syringe Disposal Patterns at a VA Hospital

Disposable plastic syringes have become the preferred method of insulin administration. Roughly, one billion are used annually in the United States. Recently, public concern has been raised over safety issues such as stolen syringes, accidental AIDS and hepatitis transmittal, and accidental puncture wounds.