LETTERS

Nifedipine in digital ulceration in scleroderma

To the Editor:

We (1,2) and others (3) have shown that the slow calcium channel blocking agent nifedipine is effective in the treatment of Raynaud's phenomenon. Dr. Jaffe's letter (4) prompts us to report our preliminary results of a single-blind study of nifedipine in the treatment of cutaneous ischemic ulceration in progressive systemic sclerosis.

We report here the results of the first 4 patients included in this study (3 female and 1 male; mean age 54 years, range 42–68). These patients met the criteria for scleroderma in accordance with the preliminary criteria for the classification of systemic sclerosis (5) (mean duration of definite scleroderma: 5.5 years, range 3–8). All had typical Raynaud's phenomenon, with a mean duration of symptoms of 25.5 years, range 12–43. All had refractory digital ulcerations. Three patients had previously been treated with penicillamine, and 1 with penicillamine and colchicine, without response. Three patients had previously been treated with various vasodilators without response. None of the patients was using other vasoactive medication during the study.

After we had obtained their informed consent, patients were entered into a prospective study with a single-blind protocol. After 1 month of baseline assessment, the single-blind trial consisted of (a) placebo 4 times a day for 6 weeks and (b) nifedipine 20 mg 4 times a day for the final 6 weeks.

At each weekly visit inquiries were made about any side effects related to treatment; cutaneous ischemic changes in the hands were recorded. Daily frequency of Raynaud's phenomenon was determined from a diary kept by the patient. The severity of digital vasospastic attacks was assessed by means of a 10 cm visual analog scale, with 0 representing minimum and 10 representing maximum severity. Drug effectiveness in the treatment of Raynaud's phenomenon was assessed by means of a similar 10 cm visual analog scale, with 0 representing no effect and 10 representing complete abolition of symptoms.

The mean daily frequency of Raynaud's phenomenon was 8.7 (range 6.9–11.1) for the baseline period, 8.8 (range 6.1–10.6) for the placebo period, and 2.7 (range 2.3–3.1) for the nifedipine period of the study. The severity of digital vasospastic attacks was 8.8 (range 8.4–9.2) for the baseline period, 8.7 (range 8.2–9.3) for the placebo period, and 2.1 (range 1.4–2.7) for the nifedipine period of the study. The patient score for drug effectiveness in Raynaud's phenomenon was 0.2 (range 0–0.9) for placebo and 6.9 (range 5.9–7.9) for nifedipine.

The mean number of digital ulcerations was 7.25 (range 6–10) at the end of the baseline period, 7.75 (range 6–10) at the end of the placebo period, and 0.5 (range 0–1) at the end of the nifedipine period of the study. At the end of the nifedipine period, all of the digital ulcers had completely healed in patients 1 and 2; 6 of the 7 digital ulcerations had completely healed in patient 3, and 5 of the 6 in patient 4.

Side effects with nifedipine occurred in the 4 patients but were generally mild, and no patient discontinued the study because of side effects. Flushing and headache occurred in 2 patients and disappeared with continued therapy. Ankle swelling occurred in 3 patients, and disappeared with continued therapy in 2 of the 3. The only side effect reported with placebo was transient dizziness in 1 patient.

At the end of the study all 4 patients chose to continue therapy with nifedipine. They were continuing nifedipine therapy 12.75 months (range 7–22 months) after the completion of the study. By 3 months, all of the ulcers had completely healed in patients 3 and 4. The dose of nifedipine was progressively decreased to 20 mg 3 times daily in 3 patients and to 10 mg 4 times daily in 1 patient. There were no signs of relapse during nifedipine therapy.

Thus, nifedipine appears to be extremely useful in the treatment of digital ulcerations in patients with progressive systemic sclerosis and severe Raynaud's phenomenon. A controlled trial of nifedipine in the treatment of cutaneous ischemic ulceration in systemic sclerosis is warranted.

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Central nervous system manifestations after pulse therapy for systemic lupus erythematosus

To the Editor:

Suchman et al (1) recently suggested a relationship between intravenous methylprednisolone pulse therapy and a seizure in a patient with systemic lupus erythematosus