

Topical versus Systemic Antimicrobial Therapy for Treating Infected Diabetic Foot Ulcers: A Randomized, Controlled, Double-blinded, Multicenter Trial of Pexiganan Cream

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Purpose: This study compared the efficacy of outpatient treatment with an investigational topical antimicrobial peptide formulation, pexiganan acetate cream, against systemic therapy with an oral fluoroquinolone antibiotic, ofloxacin, for mildly infected diabetic foot ulcers. Topical therapy focuses attention on the wound and uses new antimicrobials, while avoiding adverse effects and driving antibiotic resistance.

Methods: In two randomized, double-blind controlled trials we enrolled 835 diabetic patients with a mildly infected diabetic foot ulcer (and no osteomyelitis or severe limb ischemia) who received either the active topical agent or the active oral antibiotic, plus inactive placebos. The primary outcome of interest was clinical response to treatment, i.e., cure or improvement of the infection. Secondary outcomes were eradication of pathogens isolated at baseline and wound healing, based on a semi-quantitative scoring system.

Results Patients randomized to the two treatment arms were similar demographically and clinically. Clinical response rates in the two studies ranged from 85%-90%, and were overall statistically similar between the treatment groups. Microbiological eradication rates ranged from 42-47%, and were statistically similar for the two treatment groups. Wound healing rates were also statistically similar for the two treatment groups. Ofloxacin was associated with more insomnia, but the treatment adverse effects were otherwise similar.

Conclusions: In these two large studies topical pexiganan was overall as effective as oral ofloxacin in treating diabetic patients with a mildly infected foot ulcer. This offers an additional route of therapy and a novel class of antimicrobial agents to treat these serious infections.