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

Lipsky BA, Holroyd, KJ, Zasloff M.

BACKGROUND: Topical antimicrobial therapy of infected diabetic foot ulcers can focus on the wound and avoid the adverse effects of systemic anti-infective agents. We compared the efficacy of outpatient treatment using an investigational topical antimicrobial peptide, pexiganan acetate cream, with the efficacy of systemic therapy using an oral fluoroquinolone antibiotic, ofloxacin, for mildly infected diabetic foot ulcers.

METHODS: In 2 consecutive, double-blind, controlled trials (study 303 and study 304), we randomized diabetic patients with a mildly infected diabetic foot ulcer to receive the active topical agent or active oral antibiotic, plus a respective inactive placebo. The primary outcome of interest was clinical cure or improvement of the infection. Secondary outcomes included eradication of wound pathogens and wound healing, which was documented by a semiquantitative scoring system.

RESULTS: Overall, 835 patients were randomized; those in each treatment arm were similar with regard to demographic and clinical characteristics. Although study 303 failed to demonstrate equivalence, study 304 and the combined data for the 2 trials demonstrated equivalent results (within the 95% confidence interval) for topical pexiganan and oral ofloxacin in clinical improvement rates (85%-90%), overall microbiological eradication rates (42%-47%), and wound healing rates. The incidence of worsening cellulitis (2%-4%) and amputation (2%-3%) did not differ significantly between treatment arms. Bacterial resistance to ofloxacin emerged in some patients who received ofloxacin, but no significant resistance to pexiganan emerged among patients who received pexiganan.

CONCLUSIONS: Topical pexiganan might be an effective alternative to oral antibiotic therapy in treating diabetic patients with a mildly infected foot ulcer, and might reduce the risk of selecting antimicrobial-resistant bacteria.

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