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Single-Dose Fluconazole versus Standard Therapy for Oropharyngeal Candidiasis in HIV-Infected Patients: A Randomized, Double-Blind, Double-Dummy Trial.

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BACKGROUND: Oropharyngeal candidiasis is the most common opportunistic infection affecting patients with human immunodeficiency virus (HIV) infection. Because of convenience, cost, and reluctance to complicate antiretroviral treatment regimens, single-dose fluconazole may be a favorable regimen for treatment of moderate to severe oropharyngeal candidiasis. We conducted a prospective, randomized, double-blind, placebo-controlled trial to compare the clinical and mycological responses, relapse rates, and safety of a single 750-mg dose and a 14-day course of treatment with fluconazole.

METHODS: A total of 220 HIV-infected patients with clinical and mycological evidence of oropharyngeal candidiasis were randomly assigned in a 1:1 ratio to receive either a 750-mg single dose of orally administered fluconazole (110 patients) or 150 mg of orally administered fluconazole once per day for 2 weeks (110 patients). The primary efficacy analysis was based on clinical and mycological responses at the end of treatment. Secondary parameters were safety and relapse rate.

RESULTS: Single-dose fluconazole was equivalent to a 14-day course of fluconazole in achieving clinical and mycological cure, with clinical cure rates of 94.5% and 95.5%, respectively (odds ratio, 0.825; 95% confidence interval, 0.244-2.789; P= .99), and mycological cure rates of 84.5% and 75.5%, respectively (odds ratio, 1.780; 95% confidence interval, 0.906-3.496; P= .129). Drug-related adverse events were uncommon and were not different between the treatment groups.

CONCLUSION: A single dose of 750 mg of fluconazole was safe, well tolerated, and as effective as the standard 14-day fluconazole therapy in patients with HIV infection and acquired immunodeficiency syndrome who had oropharyngeal candidiasis coinfection.

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