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Anidulafungin versus fluconazole for invasive candidiasis.

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BACKGROUND: Anidulafungin, a new echinocandin, has potent activity against candida species. We compared anidulafungin with fluconazole in a randomized, double-blind, noninferiority trial of treatment for invasive candidiasis.

METHODS: Adults with invasive candidiasis were randomly assigned to receive either intravenous anidulafungin or intravenous fluconazole. All patients could receive oral fluconazole after 10 days of intravenous therapy. The primary efficacy analysis assessed the global response (clinical and microbiologic) at the end of intravenous therapy in patients who had a positive baseline culture. Efficacy was also assessed at other time points. **RESULTS:** Eighty-nine percent of the 245 patients in the primary analysis had candidemia only. *Candida albicans* was isolated in 62% of the 245 patients. In vitro fluconazole resistance was infrequent. Most of the patients (97%) did not have neutropenia. At the end of intravenous therapy, treatment was successful in 75.6% of patients treated with anidulafungin, as compared with 60.2% of those treated with fluconazole (difference, 15.4 percentage points; 95% confidence interval [CI], 3.9 to 27.0). The results were similar for other efficacy end points. The statistical analyses failed to show a "center effect"; when data from the site enrolling the largest number of patients were removed, success rates at the end of intravenous therapy were 73.2% in the anidulafungin group and 61.1% in the fluconazole group (difference, 12.1 percentage points; 95% CI, -1.1 to 25.3). The frequency and types of adverse events were similar in the two groups. The rate of death from all causes was 31% in the fluconazole group and 23% in the anidulafungin group (P=0.13). **CONCLUSIONS:** Anidulafungin was shown to be noninferior to fluconazole in the treatment of invasive candidiasis. (ClinicalTrials.gov number, NCT00056368 [ClinicalTrials.gov]). Copyright 2007 Massachusetts Medical Society.

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