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A Prospective, Multicenter Study of Caspofungin for the Treatment of Documented Candida or Aspergillus Infections in Pediatric Patients.

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OBJECTIVE: We evaluated the safety, tolerability, and efficacy of caspofungin in pediatric patients with invasive aspergillosis, invasive candidiasis, or esophageal candidiasis.

METHODS: This was a multicenter, prospective, open-label study in children 3 months to 17 years of age with proven or probable invasive aspergillosis, proven invasive candidiasis, or proven esophageal candidiasis. All of the patients received caspofungin 70 mg/m(2) on day 1, followed by 50 mg/m(2) per day (maximum: 70 mg/day), as primary or salvage monotherapy. Favorable response was defined as complete resolution of clinical findings and microbiologic (or radiographic/endoscopic) eradication (complete response) or significant improvement in these parameters (partial response). Efficacy was assessed at the end of caspofungin therapy in patients with a confirmed diagnosis who received >/=1 dose of caspofungin. The primary safety evaluation was the proportion of patients with clinical or laboratory drug-related adverse events.

RESULTS: Of the 49 patients enrolled, 3 were <2 years of age, 30 were 2 to 11 years of age, and 16 were 12 to 17 years of age. Forty-eight patients had confirmed disease: invasive aspergillosis (10), invasive candidiasis (37), and esophageal candidiasis (1). Eight of 10 patients with invasive aspergillosis had pulmonary involvement; 34 of 37 patients with invasive candidiasis had candidemia. Caspofungin was given for 2 to 87 days. Success at end of therapy was achieved in 5 of 10 patients with invasive aspergillosis, 30 of 37 with invasive candidiasis, and 1 of 1 with esophageal candidiasis. One patient (invasive candidiasis) relapsed during the 28-day follow-up period. Drug-related clinical or laboratory adverse events occurred in 27% and 35% of patients, respectively. There were no serious drug-related adverse events or discontinuations of caspofungin because of toxicity.

CONCLUSIONS: Caspofungin was generally well tolerated in pediatric patients aged 6 months through 17 years. Efficacy outcomes in patients with invasive aspergillosis or invasive candidiasis were consistent with previous adult studies in these indications.

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