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Liposomal amphotericin B as initial therapy for invasive mold infection: a randomized trial comparing a high-loading dose regimen with standard dosing (AmBiLoad trial).

Cornely OA, Maertens J, Bresnik M, Ebrahimi R, Ullmann AJ, Bouza E, Heussel CP, Lortholary O, Rieger C, Boehme A, Aoun M, Horst HA, Thiebaut A, Ruhnke M, Reichert D, Vianelli N, Krause SW, Olavarria E, Herbrecht R; AmBiLoad Trial Study Group.

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BACKGROUND: Treatment of invasive mold infection in immunocompromised patients remains challenging. Voriconazole has been shown to have efficacy and survival benefits over amphotericin B deoxycholate, but its utility is limited by drug interactions. Liposomal amphotericin B achieves maximum plasma levels at a dosage of 10 mg/kg per day, but clinical efficacy data for higher doses are lacking. **METHODS:** In a double-blind trial, patients with proven or probable invasive mold infection were randomized to receive liposomal amphotericin B at either 3 or 10 mg/kg per day for 14 days, followed by 3 mg/kg per day. The primary end point was favorable (i.e., complete or partial) response at the end of study drug treatment. Survival and safety outcomes were also evaluated. **RESULTS:** Of 201 patients with confirmed invasive mold infection, 107 received the 3-mg/kg daily dose, and 94 received the 10-mg/kg daily dose. Invasive aspergillosis accounted for 97% of cases. Hematological malignancies were present in 93% of patients, and 73% of patients were neutropenic at baseline. A favorable response was achieved in 50% and 46% of patients in the 3- and 10-mg/kg groups, respectively (difference, 4%; 95% confidence interval, -10% to 18%; $P>.05$); the respective survival rates at 12 weeks were 72% and 59% (difference, 13%; 95% confidence interval, -0.2% to 26%; $P>.05$). Significantly higher rates of nephrotoxicity and hypokalemia were seen in the high-dose group. **CONCLUSIONS:** In highly immunocompromised patients, the effectiveness of 3 mg/kg of liposomal amphotericin B per day as first-line therapy for invasive aspergillosis is demonstrated, with a response rate of 50% and a 12-week survival rate of 72%. The regimen of 10 mg/kg per day demonstrated no additional benefit and higher rates of nephrotoxicity.

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