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Safety and efficacy of liposomal amphotericin B for treatment of complicated visceral leishmaniasis in patients without HIV, North-West Ethiopia

Aschalew Tamiru[1], Bethlehem Tigabu[1], Sisay Yifru[1], Ermias Diro[1] and **Asrat Hailu[2]**
[1]University of Gondar, Ethiopia
[2]Addis Ababa University, Ethiopia

Background & Aim: Visceral leishmaniasis (VL) is a protozoan disease that is invariably fatal if left untreated. The disease is found in 70 countries with incidence of 0.2 to 0.4 million cases. The mainstay of treatment in resource limited countries like Ethiopia is antimonials, while use of liposomal amphotericin B is reserved for treatment of complicated VL cases. The aim of this study was to assess the safety and efficacy of liposomal amphotericin B in HIV negative VL patients diagnosed with complications.

Methods: A retrospective chart review was conducted involving records of patients admitted between January 2009 and December 2014. Baseline sociodemographic, clinical, and treatment outcome data were collected. The doses of liposomal amphotericin B and adverse events related to treatment were retrieved. Categorical and continuous variables were analyzed by Chi-square and Mann-Whitney U tests, respectively. A p-value of less than 0.05 was considered statistically significant.

Results: A total of 147 patients with severe VL were treated with liposomal amphotericin B in total dose ranges of 20 mg/kg to 35 mg/kg. In the overall treatment outcome analysis, initial cure (30 days after start of treatment) was observed in 128 (87.1%), treatment failures in 10 (6.8%), interruptions in 2 (1.4%) and deaths in 7 (4.8%) patients. Initial cure rate at high dose (24-35 mg/kg total dose) was 96.7% (59/61) versus 80.2% (69/86) at lower doses (<24 mg/kg); which was significantly higher (P<0.01), OR=4.56: 95%, Confidence Interval (CI)=1.17-20.78). Ten cases (11.8%) of treatment failure occurred in the low dose treatment group. The most common adverse events (AEs) were hypokalemia in 39 cases (26.5%) and infusion related reactions in 16 (10.9%). The frequency of hypokalemia and infusion related reactions were not significantly different between the low and high dose liposomal amphotericin B.

Conclusion: In HIV negative complicated VL patients, high dose of liposomal amphotericin B was found to have high cure rate at the end of the treatment. The appropriate dose for better efficacy needs to be determined. Monitoring serum potassium level during treatment with liposomal amphotericin B should be an essential component of the clinical management of VL.

aschex2006@yahoo.com

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