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**Thesis title:** Effectiveness and Safety of Short Course Liposomal Amphotericin B (AmBisome®) as First Line Treatment for Visceral Leishmaniasis in Bangladesh

**Key words:** Leishmaniasis; Kala Azar; Liposomal Amphotericin-B; Ambisome; Treatment; MSF

**Involved research institutions and supervisors (and their affiliation) :**

Médecins Sans Frontières - Koert Ritmeijer- University of Amsterdam, Amsterdam, The Netherlands;

**Abstract:**

**Background**

Bangladesh is one of the endemic countries for Visceral Leishmaniasis (VL). Médecins Sans Frontières (MSF) ran a VL treatment clinic in the most endemic district (Fulbaria) between 2010 and 2013 using a semi-ambulatory regimen for primary VL of 15mg/kg Liposomal Amphotericin-B (AmBisome®) in three equal doses of 5mg/kg. The main objective of this study was to analyze the effectiveness and safety of this regimen after a 12 month follow-up period by retrospective analysis of routinely collected program data. A secondary objective was to explore risk factors for relapse.

**Methods and principal findings**

Our analysis included 1521 patients who were initially cured, of whom 1278 (84%) and 1179 (77.5%) were followed-up at 6 and 12 months, respectively. Cure rates at 6 and 12 months were 98.7% (1262/1278) and 96.4% (1137/1179), respectively. Most relapses (26/39) occurred between 6 and 12 months after treatment. Serious adverse events (SAE) were recorded for 7 patients (0.5%). Odds of relapse at 12 months were highest in the youngest and oldest age groups. There was some evidence that spleen size measured on discharge (one month after

initiation of treatment) was associated with risk of relapse: OR=1.25 (95% CI 1.01 to 1.55) per cm below lower costal margin (P=0.04).

### **Conclusions**

Our study demonstrates that 15mg/kg AmBisome® in three doses of 5mg/kg is an effective (>95% cure rate) and safe (<1% SAE) treatment for primary VL in Bangladesh. The majority of relapses occurred between 6 and 12 months, justifying the use of a longer follow-up period when feasible. Assessment of risk of relapse based on easily measured clinical parameters such as spleen size could be incorporated in VL treatment protocols in resource-poor settings where test-of-cure is not always feasible.