Treatment of Indian Visceral Leishmaniasis with Miltefosine - 10 Years Later

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Early treatment is a major component of the current Kala-azar Elimination programme in the Indian sub-continent. Due to drug toxicity and emerging drug resistance, the former first-line drug sodium stibogluconate was recently replaced by miltefosine (MIL) in the Indian subcontinent. MIL is an oral drug with a long half-life, so emergence of drug resistance to MIL is a strong possibility. After a pivotal phase 3 trial 10 years ago, miltefosine was approved for clinical use in India, In Kaladrug-R project, again patients are being treated with miltefosine by directly observed therapy in the hospital. Till now, 426 parasitologically confirmed VL patients have been treated with MIL. Vomiting (33%) followed by diarrhea (2%) were the commonest adverse events. In five patients treatment was stopped due to drug toxicity. Although all patients were parasitologically negative by microscopy at the end of treatment, parasites were grown from post-treatment splenic tissue in 7 patients. From the 72 patients that were clinically assessed at 6 months post-treatment, 66 had final cure, and 6 relapsed. There were three deaths related to the serious adverse events attributed to the drug. As early trend suggest, miltefosine is still an effective therapeutic tool provided compliance is ensured.