The Utility And Efficacy Of Miltefosine As A 1st Line Therapy For Kala-Azar In Nepal

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Background: The kala-azar elimination programme in the Indian sub-continent recommends the use of miltefosine as a 1st line therapy. Currently it is being used within the public health facilities in the endemic districts in Nepal. Though considered safe, side effects are common and sometimes life threatening. Failure of therapy is usually delayed occurring months after completion of therapy. However outcome at 6 months of therapy though recommended is not routinely reported in the government reports. Objective: To ascertain the proportion of kala-azar cases being treated with of miltefosine and document the clinical outcome at 6 months after completion of therapy. Methodology: Parasitological confirmed kala-azar patients were treated with miltefosine unless contraindicated at B.P. Koirala Institute of Health Sciences, Nepal. They were followed up for 6 months and outcome was assessed, clinical and/or parasitological, at end of therapy and at 6 months. Initial cure was defined as those with resolution of clinical manifestations and negative parasitology at end of therapy. Final cure included those with initial cure and no recurrence of symptoms at 6 months. Relapse where those with initial cure but with recurrence of clinical manifestations and positive parasitology. Results: Till end of July 2010, 232 kala-azar cases recruited of which 42 were relapses (15 after miltefosine and 27 from other drugs). Of the 217 (190 new and 27 relapse) miltefosine naïve cases, only 176 (81%) were treated with miltefosine. The outcome of therapy, initial and final cure rate, with miltefosine, in per protocol analysis was 98 % and 89% respectively. So far, 110 patients were assessed for final treatment outcome. 6 cases have shown relapse. However, 8 more cases presented from this cohort with relapse between 6 and 12 months. Conclusions: As a 1st line therapy, over one-fifth of the kala-azar cases did not receive miltefosine. Within the programme the administration of the 2nd line therapy in the primary health centres is not feasible. With all the treatment failures being relapses,information of long term outcome is crucial to monitor the efficacy of miltefosine within the programme.