

Risk factors for relapse of visceral leishmaniasis after initial cure with miltefosine in India and Nepal.

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Abstract

Background: High incidence of relapse in miltefosine-treated patients in India and Nepal followed up for twelve months.

Methods: in a prospective study in seven health care structures in India and Nepal, we collected data from 1016 VL patients treated with miltefosine according to the standard treatment guidelines and recorded early and late treatment outcomes up to 12 months after the end of treatment. We investigated patient and treatment characteristics associated with VL relapse.

Results: clinical records from 78 relapse patients were compared with those of 775 patients who had no record of subsequent relapse. Relapse was 2 times more common amongst men compared to women (IRR 2.14, 95% CI 1.27-3.61), and 2 to 3 times more frequent in the 2 age groups below 15 compared to the over 25 year olds (Age 10 to 14: IRR 2.53; 95% CI 1.37-4.65 and Age 2 to 9: IRR 3.19 ; 95% CI 1.77-5.77). Previous VL history, or clinical presentation at time of diagnosis such as duration of symptoms or spleen size were no predictors of relapse.

Conclusions: age and gender were associated with increased risk of VL relapse after miltefosine, suggesting that the mechanism of relapse at the current stage is mainly immunological and that the observed increase of relapse may be partly explained by the inclusion of younger patients compared to the earlier clinical trials, rather than a decrease in efficacy of miltefosine.