Background

Nevirapine (NVP) is a component of antiretroviral (ARV) drugs that are widely used first-line in Indonesia. The effect is quite good but often cause side effects such as skin allergy or toxic to the liver. The aim of the study was to determine the risk factors of allergic and/or hepatotoxicity due to NVP among HIV-infected patients in Indonesia.

Method

A case-control study was conducted in HIV-infected patients who developed rash after taking NVP or increasing level of transaminase enzim (case) and those who did not have rash or increasing level of transaminase enzim (control).

Result

A total of 152 patients with a median (IQR) age of 33.0 (13.0) years; 87 (57.24%) male, 56 (36.84%) female and 9 (5.92%) transgender were included in the study. There were 52 patients in case group and 100 patients in control group. Median Basal metabolic rate (IQR) was 18.67 (5.92). Of all, 8 (5.30%) patients had a history of AIDS-defining illness and 12 (7.89%) patients had history of drug allergy. Median (IQR) CD4 cell counts at the time of NVP initiation was 128 (2-500) cells/mm³. Most patients experienced grade 2 skin rash (73.9%) and 4 (18.4%) experienced severe rash (grade 4); most patients experienced mild degree of hepatotoxicity (57.1%). Median time to develop rash was 14.50 (95% CI, 17.27-38.08) days.

Discussion

No risk factors identified in association with skin rash on adjusted analysis included history of drug allergy, low body weight, high CD4 cells counts, smoking, alcoholism and AIDS-defining illness. This result is in contrast with that reported among Thai and other patients. This difference could be due to differences in ethnicity and possibly genetic predispositions. Female gender and older age were significantly associated with nevirapine-related rash (p=0.004 and p=0.17), as has been reported elsewhere; and gender is thought to be related either to hormonal and cytochrome P450 metabolism differences. A cell-mediated hypersensitivity reaction has been postulated as one of the possible mechanisms for the development of NVP related skin rashes, and a genetic predisposition has been proposed which may underlie this process.

Conclusion

In Indonesia settings where patients were of drug allergy, lower body weight, higher CD4 cell count, smoking, alcoholism and AIDS-defining illness are not the risk factors for NVP-associated rash and/or hepatotoxicity.