Genotypic-guided versus Standard First-line Antiretroviral Regimen for Treatment Naive HIV-Infected Patients in Thailand: A Prospective Randomized Controlled Trial

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Background: An increase in the prevalence of primary HIV drug resistance (HIVDR) has been reported and it may be associated with poor treatment outcome of first-line antiretroviral therapy (ART). However, HIVDR testing prior to ART initiation is not routinely performed in Thailand.

Objective: We aimed to evaluate the prevalence of primary HIVDR by genotypic resistance assay of reverse transcriptase (RT) gene and the association between undetectable HIV RNA at week 24 after ART initiation and having primary HIVDR.

Methods: A prospective, multicenter, randomized, controlled trial was conducted involving newly diagnosed HIV-infected adults. Patients who were initiating ART were randomly assigned to either genotype-guided (GG) group or standard treatment (ST) group with a 1:1 allocation as per a computer generated randomization. Genotypic resistance assay was performed in all patients. The investigators in the GG group were informed the results before selecting the ART regimen. However, the results were blinded to the investigators who prescribed ART for the patients in the ST group. Factors that associated with having primary HIVDR and undetectable HIV RNA were analyzed by logistic regression.

Results: Ninety patients were enrolled and randomized to either the GG group (46 patients) or the ST group (44 patients). Of all, median age was 33 years and 83.3% were male. Median (IQR) CD4 count at HIV diagnosis was 145 (37-288) cells/mm\(^3\). Overall prevalence of primary HIVDR was 13.6% and it was not different between both groups (p=0.12). The prevalence of each HIVDR mutation was shown in Figure 1. No associated factor of having primary HIVDR was determined. By univariate logistic regression, having any primary HIVDR was not associated with undetectable HIV RNA. At week 24, 87.8% patients in GG arm and 92.5% patients in ST arm had undetectable HIV RNA (p=0.71). By multiple logistic regression, factors associated with undetectable HIV RNA were chronic HBV infection (OR 0.09; 95%CI 0.01-0.67, p=0.02) and having a history of pneumocystis pneumonia (OR 0.06; 95%CI 0.01-0.41, p <0.01).

Conclusions: The prevalence of primary HIVDR in Thailand is as high as 14%. However, no association between having primary HIVDR and undetectable HIV RNA after ART initiation was detected. Our study with larger sample size is ongoing to determine whether genotypic-guided first-line ART should be routinely performed in Thailand.
Keywords: primary HIV drug resistance, HIV treatment, Genotypic guided treatment