

Genotype-guided Versus Standard First-line Antiretroviral Regimen for Treatment Naïve HIV-infected Patients in Thailand: A Prospective Randomized Controlled Trial

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Background

- Pretreatment drug resistance (PDR): HIVDR detected among
 - Treatment naïve individuals initiating ART or
 - Individuals with prior HIV drug exposure initiating or reinitiating first-line ART
- An increase in the prevalence of PDR has been reported in many countries
- PDR may be associated with poor treatment outcome of first-line ART
- Genotypic HIVDR testing is recommended for persons with HIV infection at entry into care to guide the initial ART regimen but NOT in Thailand

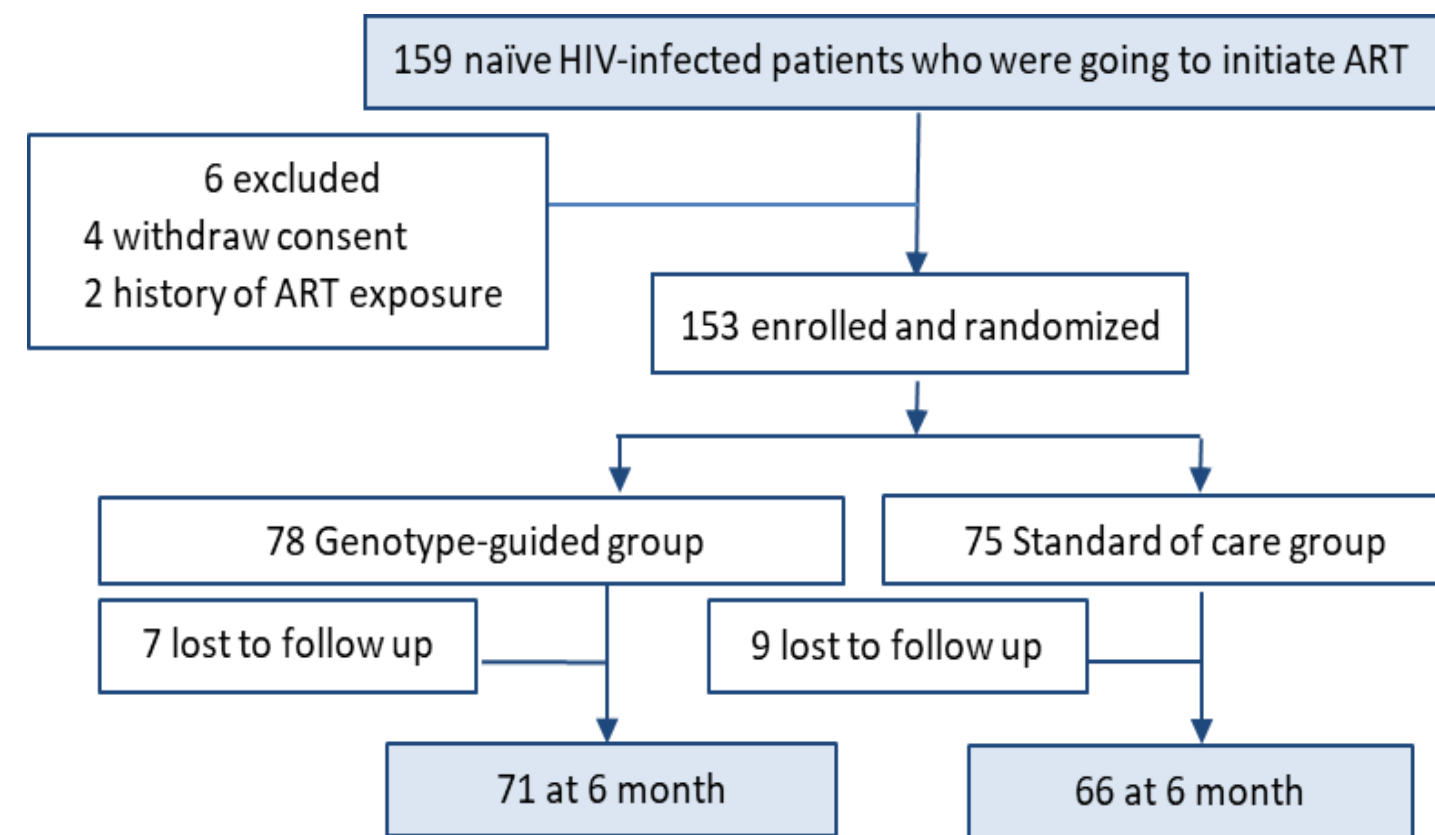
Materials & Methods

- Prospective, multicenter, randomized controlled trial
 - September 2016 to October 2017
 - Lower the cost of testing from 300 USD to approximately 40 USD by in-house testing
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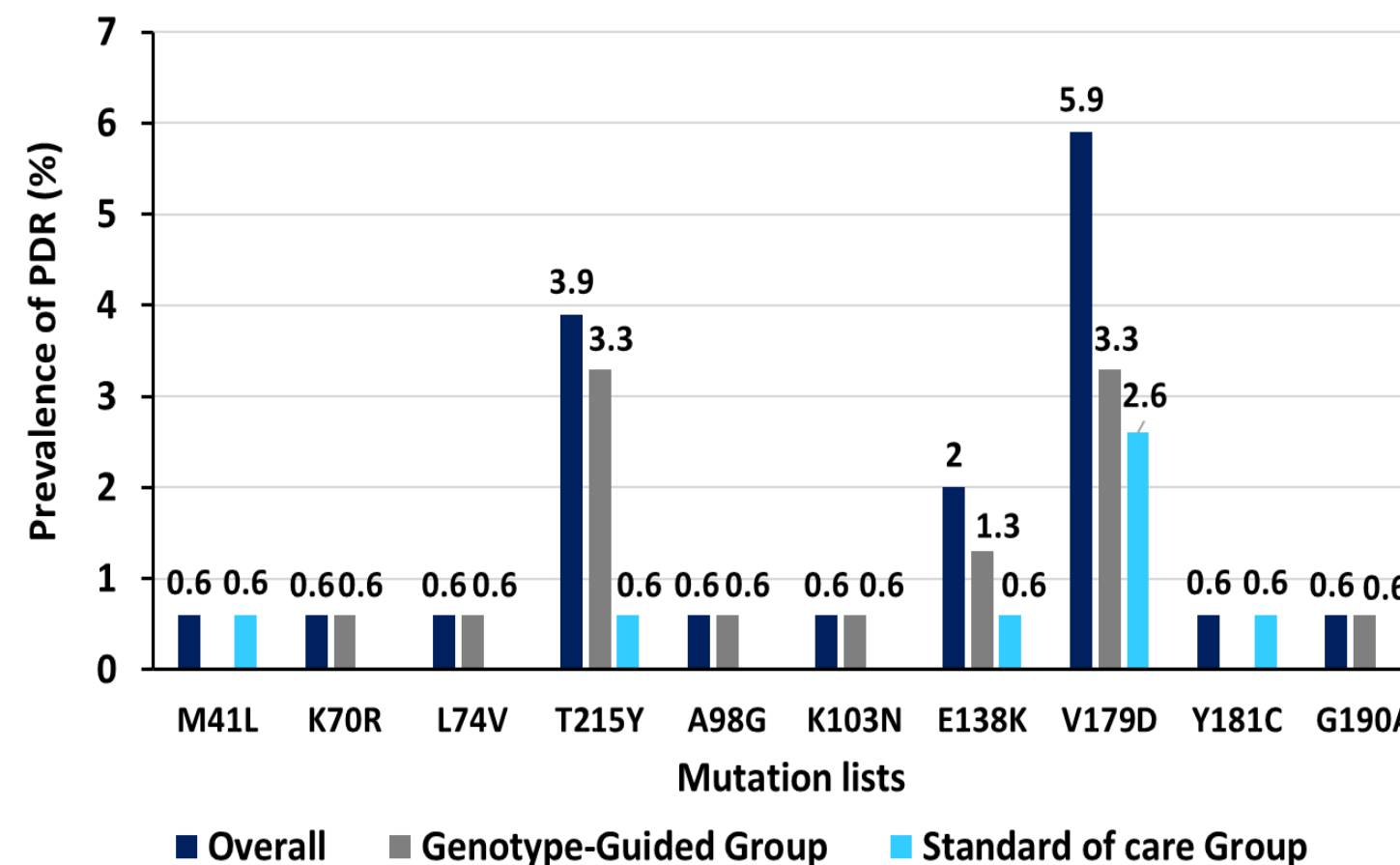
 graph TD
 A[Naïve HIV-infected patients] --> B[Genotype-guided group]
 A --> C[Standard of care group]
 B --> D[6 months]
 C --> D

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- 1:1 allocation per a computer generated block randomization
  - HIVdb program of Stanford HIV database was used to classify the DR mutations
  - Factors associated with having PDR and undetectable HIV RNA were analyzed by logistic regression

## Results



Overall prevalence of PDR: 13.7%  
Prevalence of PDR to NRTIs: 5.9%  
Prevalence of PDR to NNRTIs: 10.5%



**Table: Comparisons of clinical characteristics and laboratory investigations between patients in genotype-guided group and those in standard of care group at baseline**

| Variables                                         | Overall (N=153) | Genotype-guided group (N=78) | Standard of care group (N=75) | P-value |
|---------------------------------------------------|-----------------|------------------------------|-------------------------------|---------|
| <b>Clinical characteristics</b>                   |                 |                              |                               |         |
| Median (IQR) age, years                           | 32 (26-42)      | 35 (26-43)                   | 30 (26-38)                    | 0.090   |
| Male gender, n (%)                                | 127 (83.0)      | 60 (76.9)                    | 67 (89.3)                     | 0.041   |
| Routes of HIV acquisition, n (%)                  |                 |                              |                               |         |
| Heterosexual                                      | 75 (49%)        | 47 (60.3)                    | 28 (37.3)                     | 0.035   |
| Men who have sex with men                         | 73 (47.7)       | 26 (33.3)                    | 47 (62.7)                     |         |
| Condom usage, n (%)                               | 15 (9.8)        | 6 (7.7)                      | 9 (12.0)                      | 0.370   |
| History of opportunistic infections, n (%)        | 69 (45.1)       | 41 (52.6)                    | 28 (37.3)                     | 0.058   |
| <b>Laboratory investigations</b>                  |                 |                              |                               |         |
| Median (IQR) CD4 count, cells/mm <sup>3</sup>     | 190 (43-325)    | 152 (43-299)                 | 215 (42-351)                  | 0.304   |
| Median (IQR) HIV RNA, log <sub>10</sub> copies/mL | 5.2 (4.5-5.6)   | 5.21 (4.3-5.6)               | 5.18 (4.9-5.6)                | 0.445   |

- No factor associated with having PDR
- 76.9% of patients in genotype-guided group and 82.7% in standard of care group received TDF/FTC/EFV
- 4 (5.1%) patients in genotype-guided group needed to change the first-line regimen due to having PDR
- By multiple stepwise logistic regression analysis, factors associated with undetectable HIV RNA after 6 months of ART were adherence (OR 1.53 per 5% increment; 95% CI 1.15-2.05; p=0.004) and no history of PJP (OR 6.24; 95% CI 1.62-24.08; p=0.008)

## Conclusions

- Overall prevalence of PDR is moderate and PDR of NNRTIs is high according to WHO category
- Genotype-guided first-line ART is not associated with better outcomes compared to standard of care
- Periodically PDR surveillance as well as efficacy and cost effectiveness of genotype-guided first-line ART with larger participants should be further studied