Comparison of Phenotypic (Trofile®) and Genotypic (SensiTrop II) Assays to Determine HIV Tropism in Treatment-Naive Subjects

Michael C. McCarthy, Regis Vilchez, Jorge Quiroz, Julie Strzalk, Jennifer Liberis, and Lisa M. Dunkle
Scheuing-Plough Research Institute, Kenilworth, NJ, USA

Study Subjects and Methods

-Trofile® and SensiTrop II are two nonoverlapping technologies that determine CCR5 tropism. The Trofile® assay uses a combination of genotypic and phenotypic methods, while the SensiTrop assay uses a combination of genotypic methods and heteroduplex analysis. The combination of gp120 sequencing and heteroduplex complex formation.

-Both assays were performed on 252 paired plasma samples from treatment-naive subjects.

-Assay selection was based on the recommendation of the Clinical Trials and Antiretroviral Treatment Selection Working Group of the AIDS Clinical Trials Group (ACTG) and the National Institute of Allergy and Infectious Diseases (NIAID), as well as the recommendation of the U.S. Department of Health and Human Services (USDHHS).

-All samples were performed using the standard assay protocols, and results were compared with those of a blinded assay.

-All samples were processed and analyzed according to the manufacturer's instructions.

-Results were summarized using descriptive statistics, and comparisons were made using the Wilcoxon rank-sum test for continuous variables and the chi-square test for categorical variables.

-All statistical analyses were performed using R (version 3.1.2) and SAS (version 9.3) software.

-Evaluation of the results was performed in a blinded fashion by a blinded assessor.

-Results were compared with those of the Trofile® assay, which is considered the gold standard for determining CCR5 tropism.

-Overall, SensiTrop II reported D/M tropism more frequently than Trofile®, regardless of viral load and HIV clade.

-There were no significant differences in the proportion of samples with reportable results between the two assays.

-Overall, SensiTrop II reported D/M tropism more frequently than Trofile®, regardless of baseline viral load.

-Results were reported by Trofile® in similar proportions across all categories of baseline viral load.

-Results were significantly more concordant than those reported by SensiTrop II, which appears to be more accurate in determining CCR5 tropism.

-All results were confirmed by both assays for 211 sample pairs.

-Results were reported by Trofile® in similar proportions across all categories of baseline viral load.

-Results were significantly more concordant than those reported by SensiTrop II, which appears to be more accurate in determining CCR5 tropism.

-All results were confirmed by both assays for 211 sample pairs.

Conclusions

-Comparison of the standard Trofile® assay and the SensiTrop II assay showed that the two assays yield results that are generally concordant with each other and that the SensiTrop II assay may be more accurate in determining CCR5 tropism.

-Overall, SensiTrop II reported D/M tropism more frequently than Trofile®, regardless of baseline viral load.

-Results were reported by Trofile® in similar proportions across all categories of baseline viral load.

-Results were significantly more concordant than those reported by SensiTrop II, which appears to be more accurate in determining CCR5 tropism.

-All results were confirmed by both assays for 211 sample pairs.

References

