OKLAHOMA STATE UNIVERSITY MEDICAL CENTER / PHARMACY

Clinical utility of archived HIV-1 DNA sequencing: optimizing antiretroviral therapy in patients with a suppressed HIV viral load

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INTRODUCTION

- Viral resistance testing is a cornerstone in HIV antiretroviral (ART) therapy
- Initiation of ART in wild type HIV without previous resistance involves a standard regimen of two nucleoside reverse transcriptase inhibitors (NRTIs) and a third antiretroviral medication with an alternate mechanism of action[1]
- Recommendations regarding regimen switching in the setting of virologic suppression are not standardized, but take into account previous treatment failures, toxicities, and past resistance testing.
- Considerations regarding switching ART therapy include, but are not limited to, regimen simplification to reduce pill burden, side effects, drug interactions, and reduce costs
- Currently, there is only one genotypic assay (GA) available for patients with a viral load <500 copies per milliliter
- There is very little data surrounding the GA's clinical significance or utility in practice.
- At this time, only one study has compared resistance patterns and ART class changes of the GA[3]

OBJECTIVES

The objectives of this study are to:

- Evaluate the number of patients with a suppressed viral load 3 and 6 months after switching their ART regimen based on GA results
- Investigate the clinical utility of the GA regarding patients with suspected resistance to their current antiretroviral therapy
- Identify the impact of GA results on those patients' ART regimen and viral load.

Other specific aims of the study include:

- Identifying common indications for obtaining a GA
- Comparing ART pre- and post-GA ART regimens
- Evaluating mutations present on GA results

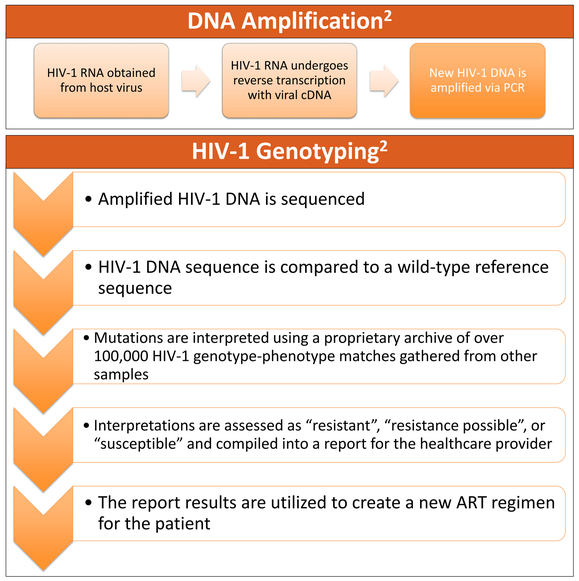
METHODS

This study is a retrospective chart review based on GA reports obtained historically through the Oklahoma State University Internal Medicine Specialty Clinic electronic medical record. Information gathered will consist of the following:

- Clinical indications for a GA
- Mutations on GA results (and on past resistance testing)
- ART regimen at the time of the GA draw
- ART regimen 3 and 6 months post-GA results
- Past ART regimens

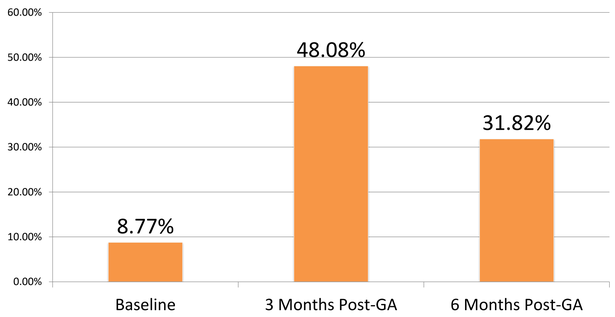
Demographic information collected will included the following: patient age, sex, ethnicity, AIDS status, HIV risk category (intravenous drug use, men who have sex with men (MSM) heterosexual individuals, or other).

Other information gathered included CD4 count at the time the GA is obtained, CD4 count 3 and 6 months after a GA was obtained, HIV RNA at the time a GA was obtained, HIV RNA 3 and 6 months after a GA was obtained, reported compliance to therapy, and patient-reported tolerability of ART regimens before and after a GA was obtained.

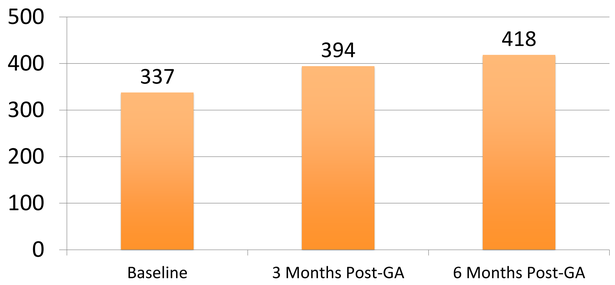


RESULTS

Percent of Patients with an Undetectable HIV RNA Viral Load

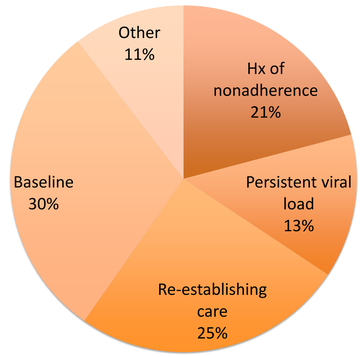


Mean CD4 of HIV Patients 3 and 6 Months Post-GA



Data were gathered from 67 patients, primarily male (87%), with an average age of 45. The most common indications for obtaining a GA were baseline testing (29.8%), re-establishing care (25.4%), and history of non-adherence (20.9%). Approximately half (49%) of patients had an undetectable viral load 3 months after switching their ART regimen based on GA results.

Indications for Obtaining a GA



CONCLUSION

- GA results can be utilized to optimize the efficacy of ART regimens for patients with HIV
- Obtaining a GA provides guidance for ART regimen switches in the setting of patients who have developed resistance to their current ART regimen
- Further study will be conducted to compile mutations most commonly observed on GA reports, quantify incidence of pill burden reduction, and compare patient-reported medication adherence and ART regimen tolerability before and after switching therapy.

REFERENCES

1. Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV*. Department of Health and Human Services.
2. Monogram Biosciences. Genosure Archive: HIV-1 Next Generation DNA Sequencing Assay.
3. Singh, Harjot, et al. Application of GenoSure Archive in Clinical Practice. *Open Forum Infectious Diseases*. Vol. 3. No. suppl 1. Oxford University Press, 2016.