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HCV GENOTYPE DIVERSITY AMONG PATIENTS TREATED WITH ANTIVIRAL MEDICATIONS IN GEORGIA

George Kamkamidze, Maia Kajaia, Tinatin Abzianidze, Ana Gamezardashvili, Lasha Gulbiani, Maia Butsashvili

Clinic NeoLab & Health Research Union, Tbilisi, Georgia

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INTRODUCTION

Georgia has a high burden of hepatitis C virus (HCV) infection. In 2015, Ministry of health of Georgia with National Center for Disease Control and Public Health (NCDC) and US Centers for Disease Control and Prevention (CDC) conducted the study where a national probability sample of approximately 6000 adults in Georgia was tested for HCV infection, yielding a prevalence estimate of 7% for chronic HCV with an estimated 5.4% of adults currently infected.

On April 28, 2015, in collaboration with CDC, Gilead Sciences and other partners, Georgia launched a comprehensive, national HCV elimination program that included free of charge treatment for all HCV infected persons. If successful, the viral reservoir will be substantially reduced and will dramatically decrease the risk of HCV transmission in the country.

Different studies suggest that antiviral treatment outcome is associated with genotype, treatment regimen and liver fibrosis stage.

Identification of HCV genotypes is important for outbreak investigations as well as for determination of antiviral treatment duration and prognosis of its outcome.

METHODS

The Elimination Program requires participating clinics and treatment sites to collect pre-treatment socio-demographic, clinical and laboratory data, prescribed medications, treatment adherence and monitoring data.

These data are collected using standardized protocols, and entered in information management system STOP-C - Georgia's national electronic treatment database, developed for the HCV elimination program.

Data collected includes HCV genotype and viral load, level of liver fibrosis, risk factors for HCV infection and treatment-related laboratory data, including SVR at week 12-24 after completion of treatment.

The Elimination Program requires all patients to have a pre-treatment FIB4 score, which is computed from age, ALT, AST and platelet count. A FIB4 score is interpreted as follows: below 1.45 (low), 1.45-3.25 (equivocal), and greater than 3.25 (advanced fibrosis). For those in the equivocal range, a liver elastography is conducted and results recorded.

Consecutive patients with HCV infection treated during 2013-2016 in outpatient clinic NeoLab, which represents one of the main sites in Georgia responsible for HCV diagnostics and treatment, have been studied. 5 ml blood from each subject has been collected in EDTA containing tubes. HCV antibodies were defined by ELISA. Samples from antibody-positive subjects were investigated by HCV RNA real-time PCR (Sacace, Italy). Among subjects positive by HCV RNA PCR the HCV genotypes have been determined by HCV genotype real-time PCR assay (Sacace, Italy) or alternatively by Versant HCV Genotype v2 (Siemens, Ghent, Belgium).

RESULTS

3310 participants were involved in study. Among them 431 (13%) were females and 2862 (87%) were males. The mean age was 44.6.

Out of 3310 patients enrolled 859 (30.1%) had genotype 1, 745 (26.1%) had genotype 2 and 1189 (41.6%) had genotype 3. Genotypes 4, 5 and 6 have not been detected in any of our patients.

Significant difference has been observed in the distribution of genotypes between the patients with and without history of intravenous drug use (IDUs).

Among 1101 patients ever using injection drugs the genotype distribution was as follows: genotype 1 – 286 (26.5%), 2 – 299 (27.7%) and 3 – 477 (44.1%), while among 764 non-IDUs the genotype distribution was as follows: genotype 1 – 277 (37.2%), 2 – 203 (27.2%) and 3 – 251 (33.7%), The difference between these two subgroups was statistically significant ($p<0.0001$).

The prevalence of mixed genotypes was significantly higher ($p<0.01$) among IDUs vs. non-IDUs.

CONCLUSIONS

Our study has shown the higher proportion of HCV genotype 3 and presence of mixture of two genotypes among IDUs in comparison with patients with no history of intravenous drug use.

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CONTACT

George Kamkamidze, MD, PhD
Director, Clinic NeoLab
47 Tashkenti Str. Tbilisi 0160 Georgia
Phone: +995 599 320303
Email: georgekamkamidze@gmail.com
www.neolab.ge