ART and long-term safety issues

OC 51 LIPID PROFILE CHANGINGS AFTER SWITCHING FROM RILPIVIRINE/TENOFOVIR DISOPROXIL FUMARATE/EMTRICITABINE TO RILPIVIRINE/TENOFOVIR ALAFENAMIDE/EMTRICITABINE: DIFFERENT EFFECTS IN DIFFERENT PATIENTS POPULATIONS. RESULTS FROM A LARGE OBSERVATIONAL STUDY

L. Taramasso[1,2], A. Di Biagio[3], N. Riccardi[2,4], F. Briano[2], E. Di Filippo[5], L. Comi[5], S. Mora[6], M. Giacomini[6], A. Gori[7], F. Maggiolo[5]

[1]Infectious Diseases Unit, Department of Internal Medicine, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy, [2]Department of Health Sciences (DISSAL), University of Genoa, Genova, Italy, [3]Infectious Diseases Clinic, Policlinico San Martino Hospital, Genoa, Italy, [4]Infectious Diseases Department, San Raffaele Scientific Institute, Milan, Italy, [5]Infectious Disease Unit, ASST Papa Giovanni XXIII, Bergamo, Italy, [6]Department of Informatics Bioengineering, Robotics, and Systems Engineering (DIBRIS), University of Genova, Genoa, Italy, [7]Infectious Diseases Unit, Department of Internal Medicine, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, University of Milan, Milan, Italy

Background: Tenofovir alafenamide (TAF) has similar efficacy compared to tenofovir disoproxil fumarate (TDF), but a less favorable effect on lipids. Aim of this study was to evaluate the impact on lipids of switching from rilpivirine (RPV)/ emtricitabine (FTC)/TDF to RPV/FTC/TAF in a large cohort of HIV-1 infected patients.

Material and methods: Retrospective study conducted in two Infectious Disease Centres in Northern Italy. All patients who switched from RPV/TDF/FTC to RPV/TAF/FTC were included. Change in lipid profile, renal function, and T-lymphocytes were evaluated at the switch and at first available follow up after the switch. Data at the two time points were compared through paired t-test, or paired samples Wilcoxon test, as appropriate. A linear regression model was used to evaluate correlations between baseline values of each variable and its change at follow up.

Results: 573 patients were considered, 99% with HIV-RNA <50 copies/ml, with mean age of 49.7 (±0.4) years and median 13.4 (6.9-22.5) years of HIV infection. After a median follow up of 12 (8-24) weeks, although mean CD4+ and CD8+ lymphocytes remained stable, (+ 8 cells/mmc and -5 cells/mmc, p= 0.4 and p= 0.6, respectively), mean CD4/CD8 ratio slightly increased (+ 0.02 p=0.001). In the same time frame the serum creatinine levels decreased from 0.96 (± 0.01) to 0.92 (± 0.01) mg/dl, p < 0.0001.

In patients with available data (431/573, 75%), mean total cholesterol (TC) changed from 173 ±1.7 to 188 ±1.8 mg/dl; mean HDL from 46 ±0.7 to 51± 0.7 mg/dl; mean LDL from 111 ±1.5 to 120 ±1.8 mg/dl; median triglycerides (TG) from 98 (75-147) to 110 (79-155) mg/dl, (p<0.0001 for all). Neither LDL/HDL nor TC/HDL ratio changed significantly. The variation in TC resulted inversely correlated to baseline TC value (R -0.252, 95% CI -0.27; -0.13, p <0.0001), as well as LDL change to LDL baseline value (R-0.238, 95%CI-0.26;-0.11, p<0.0001); HDL change to baseline HDL value (R-0.13, 95% CI-0.14;-0.02, p=0.009) and TG change at follow up to baseline TG levels (R-0.18, 95%CI -0.31;-0.10), Figure 1.

In patients with baseline diagnosis of hypercholesterolemia (TC>200 mg/dl, N=87), TC did not change, from 224±2.2 to 228±3.4 mg/dl (p=0.286), as well as LDL, from 150±2.5 to 151±3.2 mg/dl (p=0.751), while HDL increased from 51±1.6 to 55±1.7 mg/dl (p<0.0001) and both LDL/HDL and TC/HDL ratio decreased significantly, from 3.2±0.1 to 3.0±0.1 (p=0.014) and from 4.7±0.1 to 4.4±0.1 (p=0.004). In patients with baseline diagnosis of hypertriglyceridemia (TG>200 mg/dl, N= 50) TG levels did not change, from 238.5 (215 -310) to 212(163-292) mg/dl, p=0.088.

Conclusions: In this real life study, a slight increase in lipids was found after switching from RPV/FTC/TDF to RPV/FTC/TAF, but those results were not generalizable to people with hypercholesterolemia, in which lipids did not change and LDL/HDL and TC/HDL ratio decreased.