Lipid changes in HIV-patients switching to the coformulated single tablet TDF/FTC/RPV (Eviplera®). Efficacy and safety analysis. GeSida Study 8114.

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Background

Rilpivirine (RPV) has proved a better lipid profile compared with efavirenz (EFV) in naïve patients.[1,2] A recent randomized study has also shown an improvement in lipid profile after switching from a ritonavir-boosted protease inhibitor (PI/r) regimen to the coformulated emtricitabine/rilpivirine/tenofovir single-tablet (FTC/RPV/TDF).[3] Moreover, this coformulated single tablet improves adherence, and has proven its efficacy and safety.[1,3] Therefore, switching to RPV may be convenience in many patients, maintaining a good immune and virological control.

The **aim** of this study was to analyze lipid changes in HIV-patients at 24 weeks after switching to Eviplera® (emtricitabine/RPV/tenofovir disoproxil fumarate [FTC/RPV/TDF]).

Material and Methods

- Retrospective, multicenter study
- Cohort of asymptomatic HIV-outpatients on regular follow-up
- **Inclusion criteria**:
  - ✓ To have switched from a regimen based on 2 NRTI + PI/NNRTI or PI/r monotherapy to Eviplera®
  - ✓ To have an undetectable HIV viral load (< 50 cop/mL) for at least the last 3 months prior to switching
- **Exclusion criteria**:
  - ✓ Previous virologic failures on ART including TDF and/or FTC/3TC
  - ✓ Genotype tests showing resistance to components of Eviplera®
  - ✓ To have changed the third drug of the ARV regimen during the study period
- Study period: February-December /2013
- Demographic, epidemiological, clinical and analytical data
- **Changes in lipid profile** and **cardiovascular risk** (Framingham equation) and **efficacy and safety** at 24 weeks were analyzed.
- Statistic program: SPSS

Results

N= 298

Baseline characteristics	
Sex, male	242 (81.2)
Median age (years)	44.5 (37.3-50.7)
Risk behaviour for HIV infection	
IDU	63 (21.1)
MSM	135 (45.3)
HTX	91 (30.5)
Other	9 (3.0)
Time from HIV diagnosis (months)	107.6 (50.2-196-5)
AIDS cases	72 (24.2)
Lymphocyte nadir	265 (153-396)
CD4/mm3 at time of switching to Eviplera®	599 (461-798)
Time on prior ART (months)	39.4 (17.9-56.5)
Prior ART regimen	
2 NRTI + NNRTI	233 (78.2)
2 NRTI + PI/r	50 (16.8)
PI/r monotherapy	8 (2.7)
Other	7 (2.4)
Reasons for Switching to Eviplera®	
CNS adverse events	92 (31.0)
Convenience	82 (27.6)
Metabolic disorders	69 (23.2)
Other	55 (18.2)

The quantitative variables are expressed as median and IQR and the qualitative variables as n (%).
ART: antiretroviral therapy. NRTI: nucleoside reverse transcriptase inhibitors. NNRTI: non-nucleoside reverse transcriptase inhibitors. PI/r: ritonavir boosted protease inhibitors. CNS: central nervous system.
*Fixed dose emtricitabine/tenofovir 275, and fixed dose abacavir/lamivudine 12. **Efavirenz 224, etravirine 12, and nevirapine 7. ***Atazanavir 16, darunavir 11, lopinavir 11, fosamprenavir 8, and saquinavir 4. ****Darunavir 6, lopinavir 1, and atazanavir 1. *****raltegravir 5, Trizivir® 1, PI/r plus maraviroc 1

Disposition at 24 weeks*	N (%)
Patients on same regimen	281 (95.4)
Viral suppression	274 (96.8)
Treatment withdrawal	12 (4.0)
Lost to follow up	6
Adverse effects**	3
Virologic failure***	2
Abandonment	1

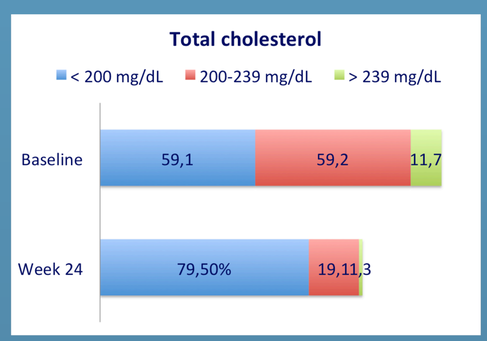
*At this time, 293 patients have reached 24 weeks
** 2 nephrotoxicity, 1 rash
***Emergence of minor resistance mutations (K70E, M230I) against efavirenz and nevirapine in one patient, and no mutations in the other one.

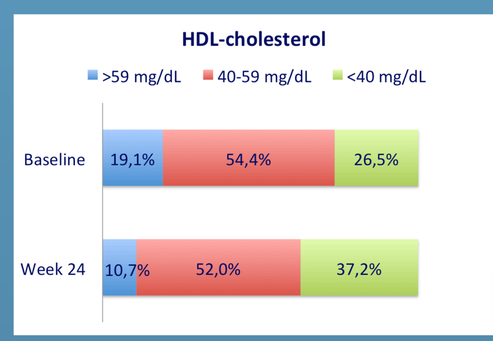
Changes from baseline to weeks 24

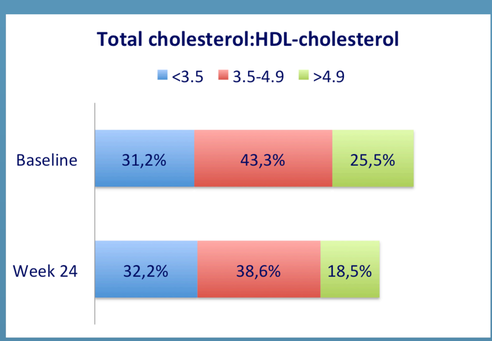
	Baseline	Week 24	P
TC (mg/dL)	193	169	0.0001
HDL-c (mg/dL)	49	45	0.0001
LDL-c (mg/dL)	114	103	0.001
TG (mg/dL)	158	115	0.0001
TC/HDL-c	4.2	4.1	0.3
CVR (%)	8.7	7.5	0.0001
CD4 (cells/µL)	653	674	0.08

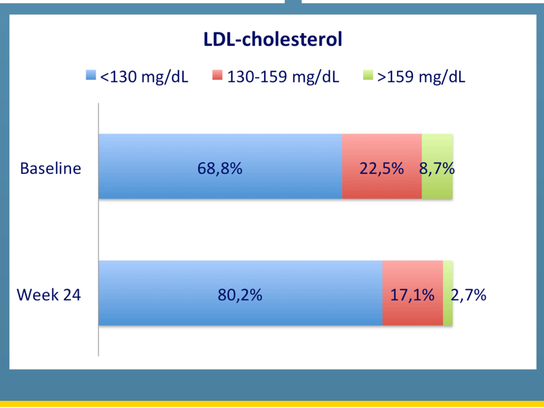
TC, total cholesterol; LDLc, low-density lipoprotein cholesterol; HDLc, high-density lipoprotein cholesterol; TG, triglycerides

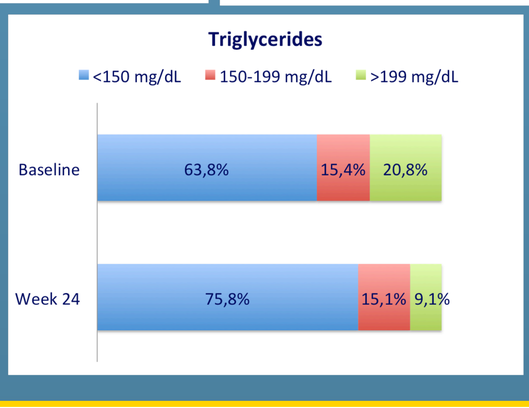
Categorical summary of fasting lipids at baseline and week 24 for the overall study population *P <0.05* for the comparison between baseline and week 24 in all categories.











Conclusions

1. At 24 weeks after switching to Eviplera®, lipid profile and CVR improved, while maintaining a good immunovirological control.
2. Most subjects switched to Eviplera® from a regimen based on NNRTI, mainly EFV/FTC/TDF.
3. CNS adverse events, convenience, and metabolic disorders were the most frequent reasons for switching.

References

1. Nelson MR, et al. Rilpivirine versus efavirenz in HIV-1-infected subjects receiving emtricitabine/tenofovir DF: pooled 96-week data from ECHO and THRIVE Studies. HIV Clin Trials 2013;14:81-91. **2.** Tebas P, et al; on behalf of the ECHO and THRIVE Studies. Lipid levels and changes in body fat distribution in treatment-naive, HIV-1–infected adults treated with rilpivirine or efavirenz for 96 weeks in the ECHO and THRIVE Trials. Clin Infect Dis 2014;59:425-434. **3.** Palella FJ, et al. Simplification to rilpivirine/emtricitabine/tenofovir disoproxil fumarate from ritonavir-boosted protease inhibitor antiretroviral therapy in a randomized trial of HIV-1 RNA-suppressed participants. AIDS 2014;28:335-344.

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