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## INTRODUCTION

- The introduction of combined ART led to substantial improvement in the prognosis of HIV/AIDS patients, with a reduction in morbidity and mortality due to opportunistic diseases and consequent improvement of the patient's quality of life.<sup>1-6</sup>
- However, HIV patients continue to present co-morbidities such as lipid disturbances, due to traditional risk factors, HIV itself and ARV therapy, as well as other toxicities of ART.

## OBJECTIVE

To analyze changes in lipid profile and tolerability in HIV-infected patients switched to rilpivirine (RPV)/emtricitabine (FTC)/tenofovir (TDF) due to intolerance to previous cART and enrolled in the PRO-STR study.

## METHODS

- PRO-STR is a 48 week observational, prospective, multicenter study.
- HIV-infected adult patients were included, with viral load <1,000 copies/mL, on stable cART ≥3 months, who switched to RPV/FTC/TDF due to intolerance to previous regimen.
- Interim analysis included 290 patients with 32 weeks of follow up.
- Fasting lipid tests were performed at baseline and between week 16 to week 32. Tolerability outcomes were analyzed from baseline to week 32.
- Means and standard deviations (SD) were used to describe continuous outcomes. Frequencies and percentages to describe categorical outcomes.
- Repeated measures multiple linear regression models, Chi<sup>2</sup> and McNemar tests were applied for inferential purposes.

## RESULTS

- 290 patients (74% male) were included:
  - 75% switched from a NNRTI (90% EFV)
  - 25% switched from a PI/r (38% TVD+DRV/r; 30% TVD+ATV/r; 19% TVD+LPV/r; 13% other).

Table 1. Patients characteristics

Age, mean (median) ± SD*		45.87 (46.00) ± 8.52
Gender, n (%)	Female	75 (25.9)
	Male	215 (74.1)
Degree, n (%)	No education	19 (6.6)
	Primary education	97 (33.4)
	Secondary education	101 (34.8)
	Higher education	73 (25.2)
Employment status, n (%)	Self-employed / Salaried	189 (65.2)
	Housewife	13 (4.5)
	Unemployed	48 (16.6)
	Pensioner / disability	36 (12.4)
	Other	4 (1.4)
Co-infections, n (%)	Hepatitis B Virus (HBV)	12 (4.1)
	Hepatitis C Virus C (HCV)	38 (13.1)
	No co-infections	242 (83.4)
Previous treatment, n (%)	NNRTI	218 (75.2)
	PI/r	72 (24.8)

Table 2: Symptoms at Baseline according to previous treatment

Neuropsychiatric intolerances description in NNRTI patients (%)	
Sleep disorders	57.3
Mood alterations	30.9
Neuro-cortical	14.1
Neuro-motor	4.7
Others*	2.9
Undefined	8.8
*Vertigo, memory leak, poor visualization, tinnitus	
Gastrointestinal intolerances description in PI+RTV patients (%)	
Diarrhoea	66.0
Abdominal discomfort	9.0
Nausea	6.0
Others*	11.4
Undefined	11.4
*Dyspepsia, epigastralgia, bitter taste	
Metabolic intolerances description in PI+RTV patients (%)	
Dyslipidemia	31.8
Hypercholesterolemia	31.8
Hypertriglyceridemia	27.3
Jaundice	13.6
Others*	18.2
*Lipo accumulations, lipodystrophy, renal lithiasis, nephritic colics	

Figure 1: Lipid changes (mg/mL) in patients switching from NNRTI

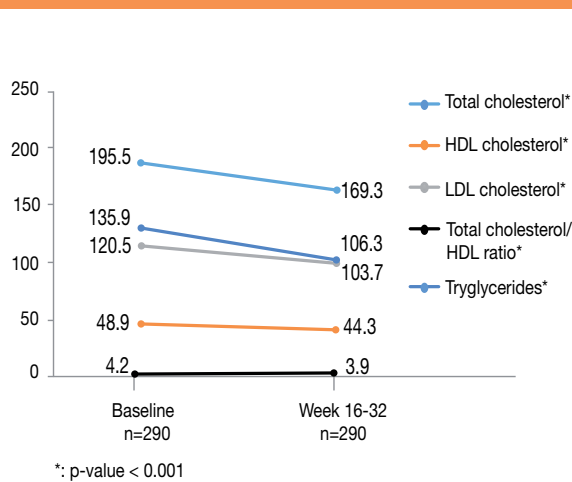


Figure 2: Lipid changes (mg/mL) in patients switching from PI/r

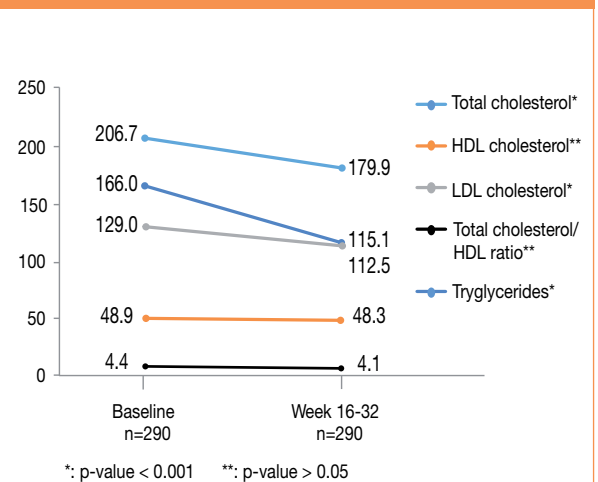


Figure 3: Evolution of symptoms in patients switching from NNRTI

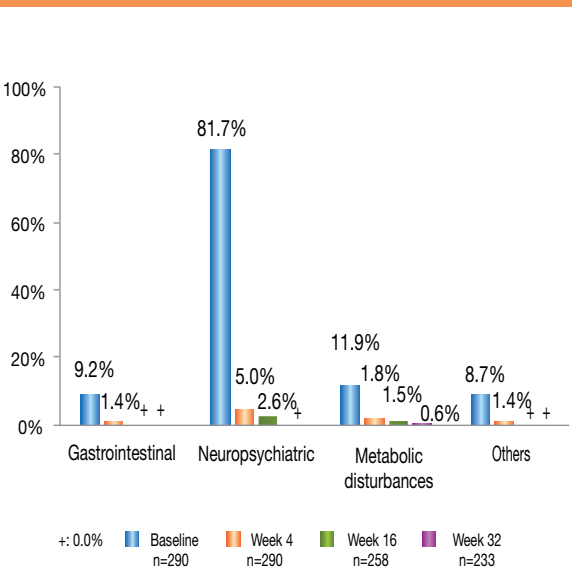
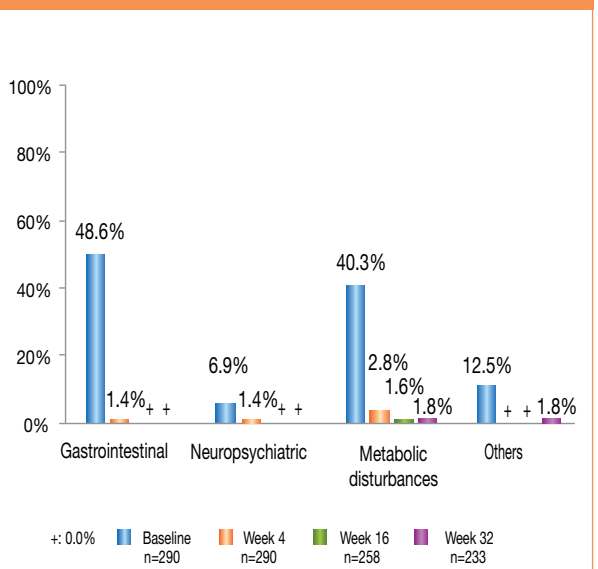


Figure 4: Evolution of symptoms in patients switching from PI/r



## CONCLUSIONS

Switching to RPV/FTC/TDF from a NNRTI or PI/r regimen due to intolerance, led to significant improvements in lipids. In addition, patient-reported neuropsychiatric and gastrointestinal symptoms resolved and only a few patients still had metabolic alterations.

## REFERENCES

- Boccarda F. Cardiovascular complications and atherosclerotic manifestations in the HIV-infected population: type, incidence and associated risk factors. *AIDS*. 2008;3:S19-26.
- Mehta N, Reilly M. Atherosclerotic cardiovascular disease risk in the HAART-treated HIV-1 population. *Clin Trials*. 2005;6:5-24.
- Hoffmann C, Jaeger H. Cardiology and AIDS -HAART and the consequences. *Ann N Y Acad Sci*. 2001;946:130-44.
- Leonard EG, McComsey GA. Metabolic complications of antiretroviral therapy in children. *Pediatr Infect Dis J*. 2003;22:77-84.
- Florida M, Tamburrini E, Ravizza M, Tibaldi C, Ravagni Prober MF, Anzidei G, et al. Lipid profile during pregnancy in HIV-infected women. *HIV Clin Trials*. 2006;7:184-93.
- Kramer AS, Lazzarotto AR, Sprinz E, Manfroi WC. Metabolic abnormalities, antiretroviral therapy and cardiovascular disease in elderly patients with HIV. *Arq Bras Cardiol*. 2009;93:561-8.

## PRO-STR STUDY GROUP

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