

LIPID CHANGES AND TOLERABILITY IN A COHORT OF ADULT HIV-INFECTED PATIENTS SWITCHING TO RPV/FTC/TDF, DUE TO INTOLERANCE TO PREVIOUS cART. A SUBSTUDY OF THE PRO-STR STUDY

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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.¹⁻⁶
- 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, Chi² 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

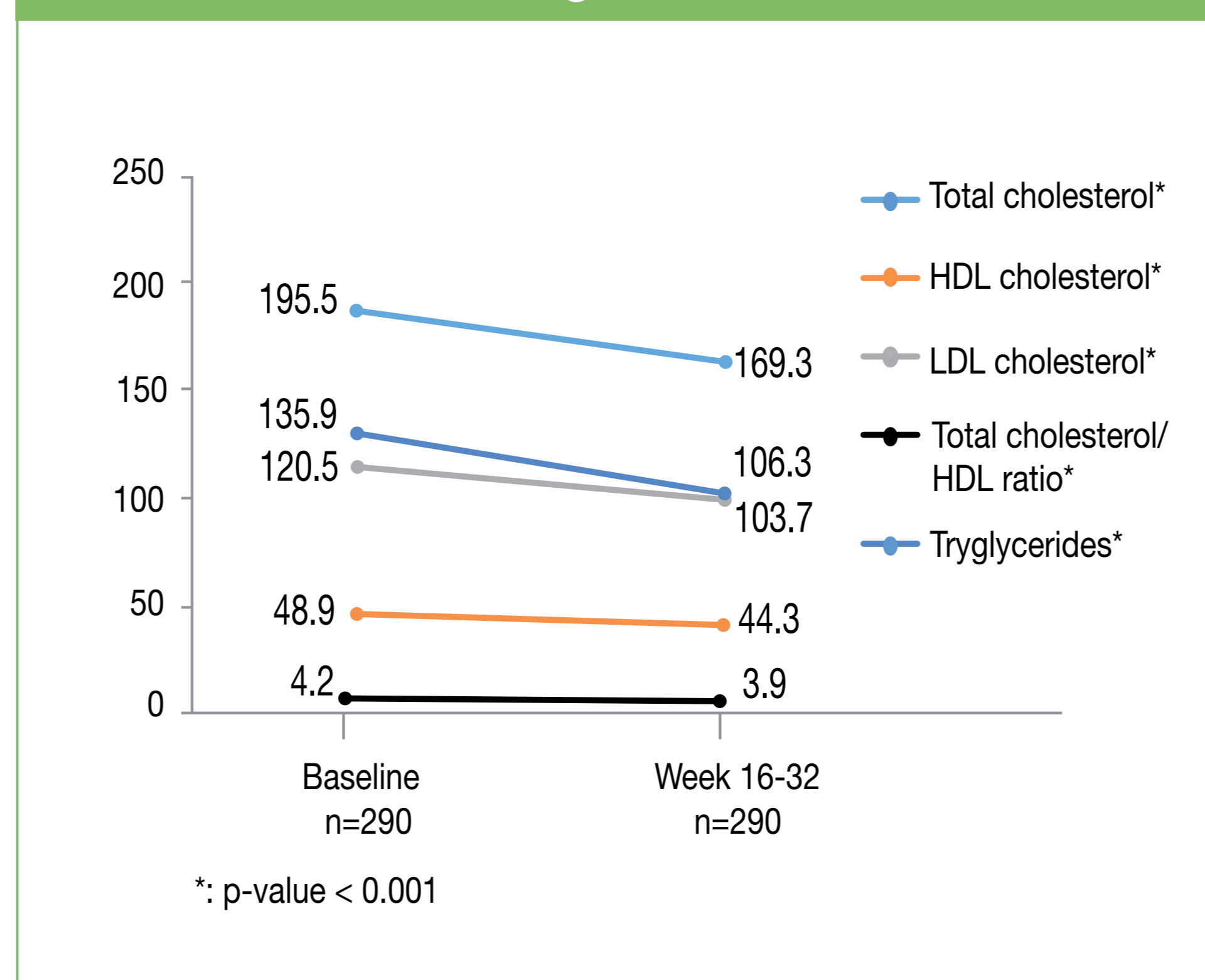


Figure 2: Lipid changes (mg/mL) in patients switching from PI/r

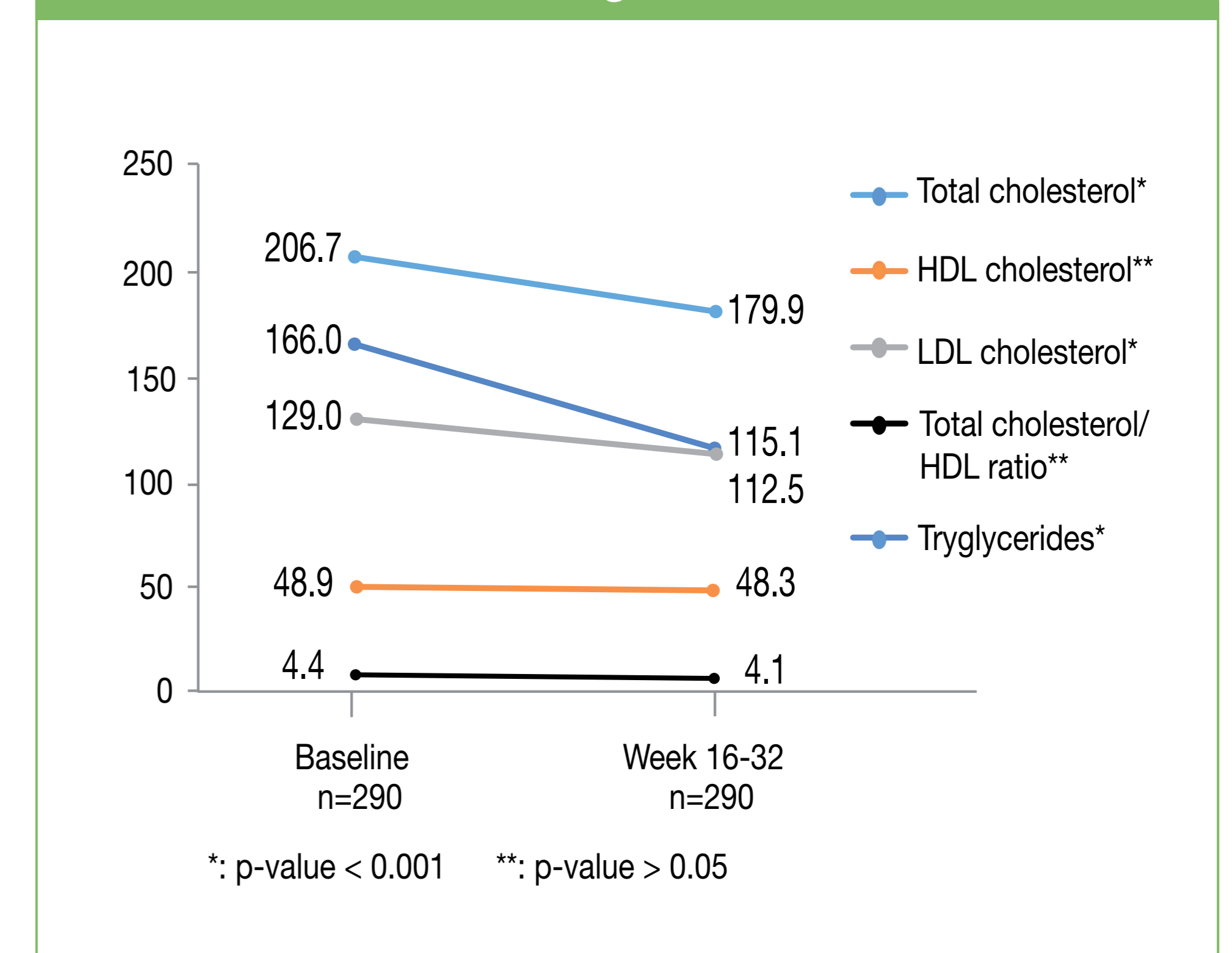


Figure 3: Evolution of symptoms in patients switching from NNRTI

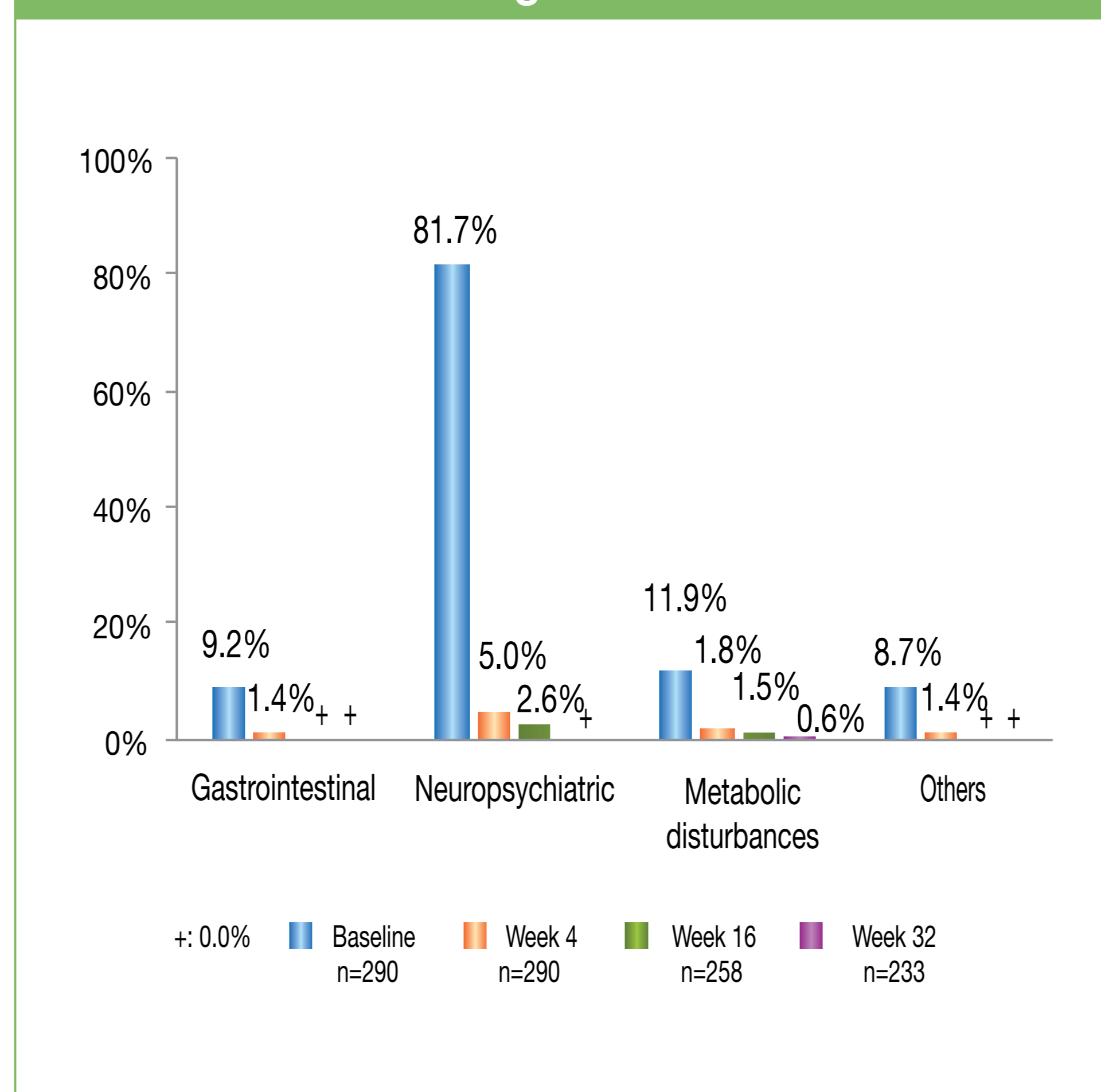
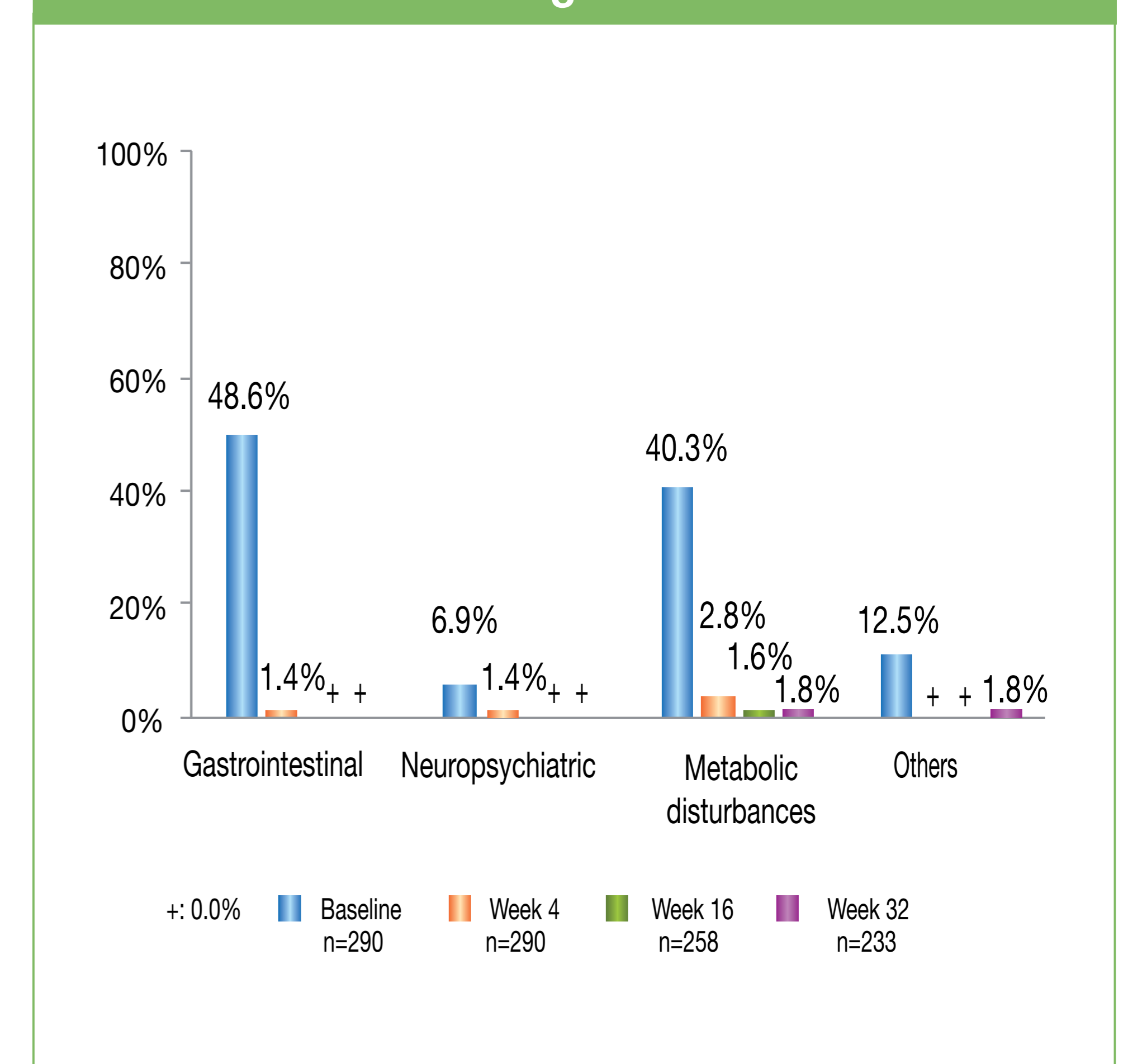


Figure 4: Evolution of symptoms in patients switching from PI/r



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.

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