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Poster Sessions – Abstract P282

ACTG-HIV symptoms changes in patients switched to RPV/FTC/TDF due to previous intolerance to CART. Interim analysis of the PRO-STR study

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Introduction: Tolerability and convenience are crucial aspects for the long-term success of combined antiretroviral therapy (cART). The aim of this study was to investigate the impact in routine clinical practice of switching to the single tablet regimen (STR) RPV/FTC/TDF in patients with intolerance to previous cART, in terms of patients' well-being, assessed by several validated measures.

Methods: Prospective, multicenter study. Adult HIV-infected patients with viral load under 1.000 copies/mL while receiving a stable ART for at least the last three months and switched to RPV/FTC/TDF due to intolerance of previous regimen, were included. Analyses were performed by ITT. Presence/magnitude of symptoms (ACTG-HIV Symptom Index), quality of life (EQ-5D, EUROQoL & MOS-HIV), adherence (SMAQ), preference of treatment and perceived ease of medication (ESTAR) through 48 weeks were performed.

Results: Interim analysis of 125 patients with 16 weeks of follow up was performed. 100 (80%) were male, mean age 46 years. Mean CD4 at baseline was 629.5 ± 307.29 and 123 (98.4%) had viral load <50 copies/mL; 15% were HCV co-infected. Ninety two (73.6%) patients switched from a NNRTI (84.8% from EFV/FTC/TDF) and 33 (26.4%) from a PI/r. The most frequent reasons for switching were psychiatric disorders (51.2%), CNS adverse events (40.8%), gastrointestinal (19.2%) and metabolic disorders (19.2%). At the time of this analysis (week 16), four patients (3.2%) discontinued treatment: one due to adverse events, two virologic failures and one with no data. A total of 104 patients (83.2%) were virologically suppressed (<50 copies/mL). The average degree of discomfort in the ACTG-HIV Symptom Index significantly decreased from baseline (21 ± 15.55) to week 4 (10.89 ± 12.36) & week 16 (10.81 ± 12.62), $p < 0.001$. In all the patients, quality of life tools showed a significant benefit in well-being of the patients (Table 1). Adherence to therapy significantly and progressively increased (SMAQ) from baseline (54.4%) to week 4 (68%), $p < 0.001$ and to week 16 (72.0%), $p < 0.001$.

Conclusions: Switching to RPV/FTC/TDF from another ARV regimen due to toxicity, significantly improved the quality of life of HIV-infected patients, both in mental and physical components, and improved adherence to therapy while maintaining a good immune and virological response.

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Table 1. Changes in quality of life tests alter switching to RPV/FTC/TDF

	(*n* = 125)						
Quality of life tools	**Baseline Average (median) ± sd**	**Week 4 visit Average (median) ± sd**	**Δ**	**p**	**Week 16 visit Average (median) ± sd**	**Δ**	**p**
MOS-HIV							
Physical component	81.28 (83.14) 9.80	84.84 (86.34) 10.23	3.56%	0.007	86.82 (87.16) 16.98	5.54%	0.003
Mental component	71.31 (75.10) 13.47	76.68 (78.37) 13.61	5.37%	0.001	77.27 (78.88) 10.14	5.96%	<0.001
EQ-5D							
EQ-5D Index Score/Value (population-based preference weights)	0.81 (0.80) ± 0.21	0.89 (1.0) ± 0.17	0.08	<0.001	0.92 (1.00) ± 0.14	0.11	<0.001
EUROQoL							
Index Score	73.29 (75.00) ± 17.93	77.33 (80.00) ± 17.06	4.04	0.001	80.60 (80.00) ± 14.22	7.31	<0.001