PE8/31

CLINICAL DATA AND PATIENT-REPORTED OUTCOMES (PRO) IN HIV-INFECTED ADULTS SWITCHING TO RPV/FTC/TDF, DUE TO A PREVIOUS INTOLERANCE TO cART. INTERIM ANALYSIS OF THE PRO-STR STUDY

Correspondence to:
Daniel Podzamczer, MD, PhD
Infectious Disease Service.
Hospital de Bellvitge.
L'Hospitalet del Llobregat. 08907
Barcelona. SPAIN.
Fax: 34-932607669
e-mail: dpodzamczer@bellvitgehospital.cat

Podzamczer D[1], Rozas N[1], Domingo P[2], Ocampo A[3], Van den Eynde E[1], Vergara A[4], Deig E[5], Knobel H[6] , Pasquau J[7], Antela A[8], Crespo M[9], Clotet B[10], Geijo P[11], Rodríguez de Castro E[12], Casado A[13]

[1]Hospital Universitari de Bellvitge, Barcelona, Spain; [2]Hospital de la Santa Creu y Sant Pau, Barcelona, Spain; [3]Hospital Xeral de Vigo, Pontevedra, Spain; [4]Hospital de Especialidades de Puerto Real, Cádiz, Spain; [5]Hospital General de Granollers, Barcelona, Spain; [6]Hospital del Mar, Barcelona, Spain; [7]Hospital Universitario Virgen de las Nieves, Granada, Spain; [8]Complejo Hospitalario Universitario de Santiago, A Coruña, Spain; [9]Hospital Universitari Vall d'Hebron, Barcelona, Spain; [10]Hospital Universitari Germans Trias i Pujol, Barcelona, Spain; [11]Hospital Virgen de la Luz, Cuenca, Spain; [12]Hospital Mateu Orfila, Mahon, Spain; [13]Pharmacoeconomics & Outcomes Research Iberia, Madrid, Spain

INTRODUCTION

- Tolerability and convenience are important for the long term success of combined antiretroviral therapy (cART).
- In the context of highly effective antiretroviral therapies, which greatly improve the survival of HIV-infected subjects, measurement of patient reported outcomes (PRO) has become an important endpoint to be assessed in clinical trials.

OBJECTIVE

To investigate the impact of switching to the single tablet regimen (STR) rilpivirine (RPV)/emtricitabine (FTC)/tenofovir (TDF) on patient reported outcomes (PRO) in HIV-infected adults, in routine clinical care who cannot tolerate previous cART.

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 of: 290 patients with complete visits at baseline and week 4; 258 patients with 16 weeks of follow up; and 233 patients with 32 weeks of follow up.
- Presence/magnitude of symptoms (ACTG-HIV Symptom Index), health-related quality of life (HRQL: EQ-5D, EQ-VAS, MOS-HIV), adherence (SMAQ), preference of treatment and perceived ease of medication (ESTAR) were assessed.

RESULTS

Table 1: Baseline characteristics of the 290 subjects included

Male **gender**, n(%)	215 (74.1)
Age, median (IQR)	45.80 (46.00, 12.00)
Education level, n(%)	
Elementary or less	116 (40.0)
Secondary	101 (34.8)
University	73 (25.2)
Hepatitis B coinfection, n(%)	12 (4.1)
Hepatitis C coinfection, n(%)	38 (13.1)
Years since HIV diagnosis, median (IQR)	11.80 (10.00, 11.00)
Years on ART, median (IQR)	8.22 (6.78, 8.56)
Years on last ART, median (IQR)	4.02 (4.05, 3.33)
Number of previous ART regimens, median (IQR)	2.54 (2.00, 2.00)
Type of intolerance to previous ART, n(%) ()	
Gastrointestinal	55 (19,0)
Central nervous system-psychiatry	183 (63,1)
Metabolic	55 (19,0)
Others	28 (9,7)
Previous ART components, n (%)	
Tenofovir/Emtricitabine (or lamivudine)	269 (92.8)
Abacavir/lamivudine	17 (5.9)
Didanosine/lamivudine	2 (0.7)
Zidovudine/lamivudine	2 (0.7)
Efavirenz	197 (67.9)
Nevirapine	12 (4.1)
Etravirine	9 (3.1)
Lopinavir/r	17 (5.9)
Darunavir/r	30 (10.3)
Atazanavir/r	22 (7.6)
Fosamprenavir/r	3 (1.0)
Ritonavir	53 (18.3)

Table 2: Viral load and CD4 count load at baseline and follow up

	Baseline n=290	Week 4 n=290	Week 16 n=258	Week 32 n=233
Viral load, n (%)*				
≤ 50 copies/mL	284 (97.9)	264 (94.0)	219 (96.0)	217 (95.6)
51-1000 copies/mL	6 (2.1) [a]	14 (5.0) [b]	7 (3.1) [d]	9 (4.0) [f]
> 1000 copies/mL	0 (0.0)	3 (1.1) [c]	2 (0.9) [e]	1 (0.4) [f]
No data available	0	9	30	6
CD4 cell count, median (IQR)**	662.5 (414.0)	646.0 (404.0)	682.0 (473)	667.0 (427)
CD4 cell count, n (%)*				
≤ 200	7 (2.4)	5 (2.0)	1 (0.5)	2 (1.0)
201-350	25 (8.7)	14 (5.6)	14 (7.2)	12 (5.8)
351-500	48 (16.8)	35 (14.1)	23 (11.9)	28 (13.6)
> 500	206 (72.0)	195 (78.3)	156 (80.4)	164 (79.6)
No data available	4	41	64	27

*Percentages were calculated excluding patients without data; **Interquartile range; [a]4/6 had VL < 50 c/mL at next visit, 2/6 no data at next visit; [b]10/14 had VL < 50 c/mL at next visit, 4/14 no data at next visit; [c]1/3 had confirmed virologic failure and the patient discontinued treatment, 1/3 had VL < 50 c/mL at next visit, 1/3 had VL >1000 c/mL at next visit; [d]3/7 VL had < 50 c/mL at next visit, 1/7 had VL 51-1000 c/mL at next visit, 3/7 had no data at next visit; [e]1/2 had VL < 50 c/mL at next visit, 1/2 had confirmed virologic failure and the patient discontinued treatment; [f]follow up viral loads after Week 32 not yet available.

Figure 1: ACTG-HIV Symptom Index

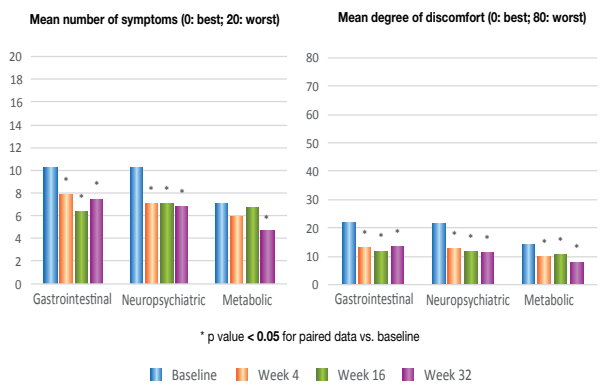


Figure 2: Quality of life (EQ-5D)

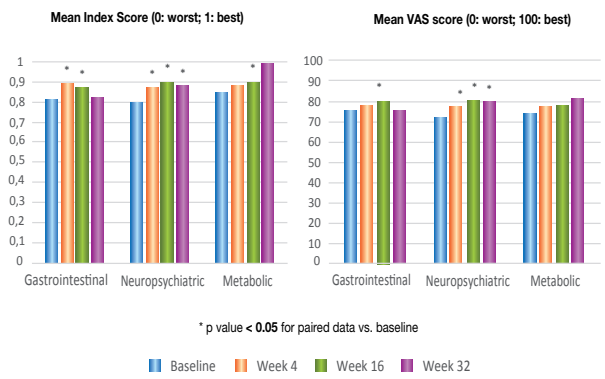


Figure 3: Quality of life (MOS-HIV)

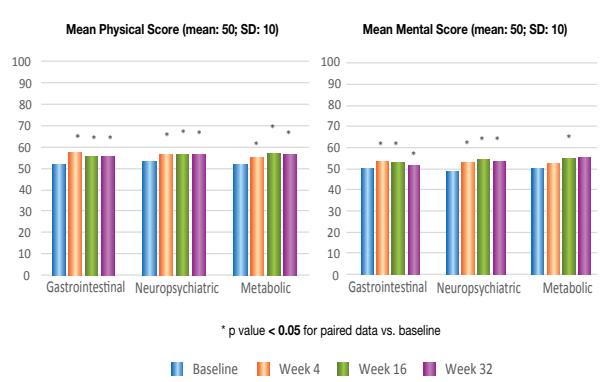


Figure 4: SMAQ: % adherent subjects

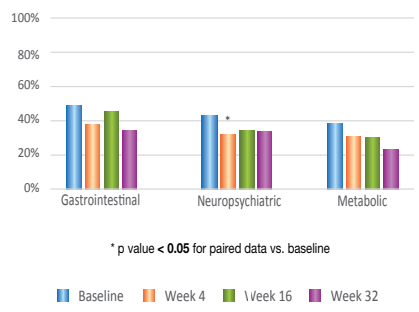


Figure 5: ESTAR: Satisfaction with treatment

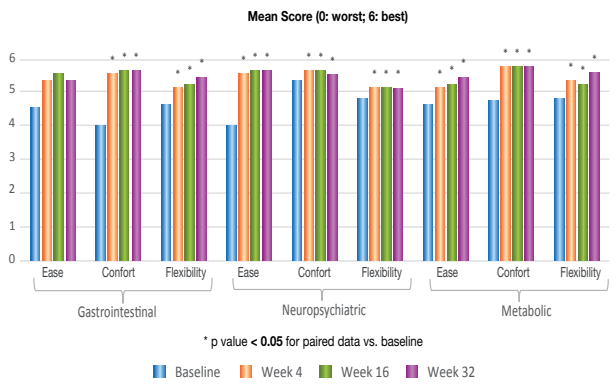
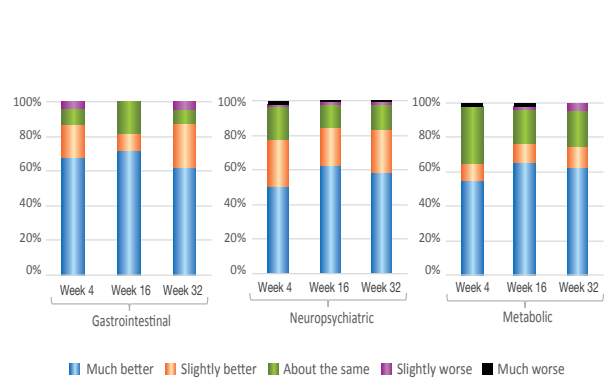


Figure 6: Preference of treatment (compared to previous regimen)



CONCLUSIONS

Switching to RPV/FTC/TDF from their previous cART due to toxicity, significantly improved the presence/magnitude of symptoms, HRQL, and a preference with treatment. RPV/FTC/TDF mantained the virologic response and CD4 counts in almost all patients.

PRO-STR STUDY GROUP

Daniel Podzamczer (PRO-STR Study Group Coordinator; H Bellvitge), Nerea Rozas, Eva van der Eynde (H Bellvitge); Pere Domingo, Jessica Muñoz (H Sant Pau); Antonio Ocampo, Fernando Warncke (H Xeral de Vigo); Antonio Vergara, Javier Borrallo (H Puerto Real); Elisabeth Deig, Maribel Tamayo (H Granollers); Hernando Knobel, Judit Villar, Alicia González (H del Mar); Antonio Antela (H Santiago de Compostela); Juan Pasquau, Coral García (H Virgen de las Nieves); Manuel Crespo, Ariadna Torrella (H Vall d'Hebron); Bonaventura Clotet, Jordi Puig, Ana Chamorro (H Germans Trias i Pujol); Paloma Geijo (H Virgen de la Luz); Eduardo Rodríguez de Castro (H Mateu Orfilia); Pedro Fernández (H Can Misses); Julio Diz (H Montecelo); José Ramón Barberá (H La Mancha Centro); María Antonia Sepúlveda (H Virgen de la Salud); Xavier Salgado, Carol Batlle (H Dr. Josep Trueta); Manuel Rodríguez, Miguel Torralba, Alfredo Espinosa, Lorenzo Sánchez (H Guadalajara); Miguel Yzusqui (H Ntra. Sra. Del Prado); Jesús Santos (H Virgen de la Victoria); Manuel Castaño, Marisa Mayorga (H Carlos Haya); Alberto Bahamonde (H Bierzo); Juan F. Lorenzo (H Burgos); Elisa Martínez (H Albacete); Pablo Bachiller (H Río Hortega).