#P089

Profile of people with HIV (PWH) switching prior antiretroviral treatment (ART) to a doravirine (DOR)-based regimen in the real-world clinical setting in Greece: The DORAVITO study

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Introduction

- DOR is a new generation non-nucleoside reverse transcriptase inhibitor, which has emerged as an option for PWH owing to its favorable safety/efficacy profile, unique resistance pathway and limited drug-drug interactions.
- This study aimed at better understanding DOR-based treatment use in Greece, focusing on characteristics of PWH, and drivers of treatment switch.

Materials and methods

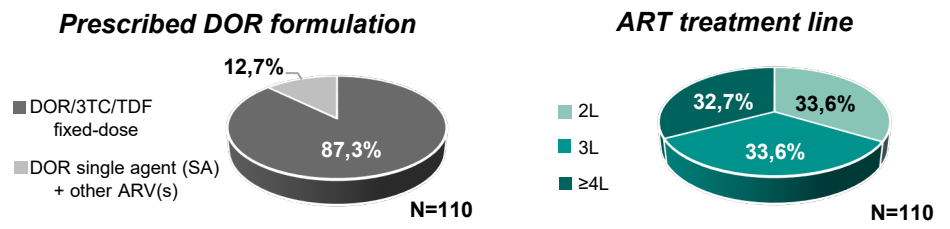
- DORAVITO was a **cross-sectional retrospective chart review** study, with a planned consecutive enrollment of 100 PWH.
- Eligible individuals were **PWH**, aged ≥18 years, who were **switched to a DOR-based regimen** based on physician's decision; the switch should have occurred in the post-marketing setting and ≥30 days before site initiation.
- Individuals exposed to DOR at any time in the past before switching to the DOR-based regimen were excluded.
- **Observation period** = initial HIV-1 diagnosis → date of first DOR prescription.
- **Baseline** = closest prior to or on date of first DOR prescription

Results

Disposition & treatment characteristics

- From 12-Jul-2023 to 31-Oct-2023, 110 PWH were enrolled across 6 public hospital clinics [academic institution, n=64 (58.2%); Inside Attica, n=98 (89.1%)]
- Most PWH (87.3%) were prescribed the fixed-dose combination (FDC) of DOR/3TC/TDF (Figure 1).
- All but 2 (98.2%) were prescribed DOR in combination with two NRTIs (Figure 1).
- PWH started DOR a **median of 11.7 years after first-ever ART initiation**, with a median (IQR) number of prior ART regimens of 2.0 (1.0-3.0) and 66.4% being prescribed in 3L (line) or ≥4L (Figure 1).

Figure 1. Distribution per formulation, ART treatment line, and drug class components of the prescribed DOR-based regimen.



DOR/3TC/TDF fixed-dose (N=96)

- FDC only, n=93 (**96.9%**)
- + INSTI, n=2 (**2.1%**)
- + entry inhibitor, n=1 (**1.0%**)

Note: Dual NRTI as part of the multi-tablet regimen

prior ART regimens, median (IQR): 2.0 (1.0-3.0)
≥2 prior ART regimens: 64.6%

Start of 1st ART → DOR initiation:
median (IQR) of 10.4 (5.9-13.9) years

DOR SA + other ARV(s) (N=14)

- + 2 NRTIs, n=11 (**78.6%**)
- + 2 NRTIs + INSTI, n=1 (**7.1%**)
- + INSTI, n=1 (**7.1%**)
- + PI + INSTI + boosting agent, n=1 (**7.1%**)

prior ART regimens, median (IQR): 3.0 (2.0-5.0)
≥2 prior ART regimens: 78.6%

Start of 1st ART → DOR initiation:
median (IQR) of 14.1 (11.7-20.3) years

DOR use in 2L (N=37)

- + 2 NRTIs, n=37 (**100.0%**)

Start of 1st ART → DOR initiation:
median (IQR) of 4.2 (1.8-12.2) years

DOR use with NRTIs in ≥3L (N=71)

- + 2 NRTIs only, n=67 (**94.4%**)
- + 2 NRTIs + INSTI, n=3 (**4.2%**)
- + 2 NRTIs + entry inhibitor, n=1 (**1.4%**)

Note: median (IQR) number of prior ART regimens: 2.0 (2.0-4.0)

Start of 1st ART → DOR initiation:
median (IQR) of 12.8 (8.9-15.8) years

DOR use without NRTI in≥3L (N=2)

- + INSTI in 4L, n=1
- + PI + INSTI + boosting agent in 7L, n=1

Start of 1st ART → DOR initiation:
10.7 and 27.5 years, respectively

Results

Characteristics of PWH

- Baseline characteristics are shown in Table 1.

Table 1. Demographic and clinical characteristics at baseline

		Overall	Formulation		ART treatment line		
			DOR/3TC/TDF fixed dose	SA + other ARV(s)	DOR+2 NRTI in 2L	DOR+2 NRTI in >2L	DOR+other ARV in >2L
		(N=110)	(N=96)	(N=14)	(N=37)	(N=71)	(N=2)
Age, mean (SD), years		49.3 (10.8)	48.6 (10.5)	54.6 (11.5)	43.1 (11.2)	52.0 (8.2)	N/A[e]
Male sex assigned at birth, %		90.9	91.7	85.7	86.5	93.0	100.0
Greek ethnic origin, %		75.5	75.0	78.6	59.5	83.1	100.0
HIV clinical stage, %	Asymptomatic	88.2	87.5	92.9	91.9	85.9	100.0
	Symptomatic[a]	8.2	8.3	7.1	5.4	9.9	.
	AIDS	3.6	4.2	.	2.7	4.2	.
Available virologic suppression status[b]		n=89	n=75	n=14	n=33	n=54	n=2
Virologically suppressed, %[c]		86.5	86.7	85.7	84.8	90.7	.
Available immunological testing in the last 6 months		n=95	n=81	n=14	n=35	n=58	n=2
CD4+ absolute count (cells/mm^3), mean (SD) [c]		697.2 (304.6)	689.1 (307.4)	744.2 (294.2)	628.6 (275.7)	738.7 (317.5)	N/A[f]
HCV / HBV, %		5.5 / 3.6	5.2 / 3.1	7.1 / 7.1	8.1 / .	4.2 / 5.6	. / .
Presence of multimorbidity[d], %		33.6	30.2	57.1	16.2	40.8	.
CCI score ≥3 %		15.5	14.6	21.4	8.1	18.3	50.0

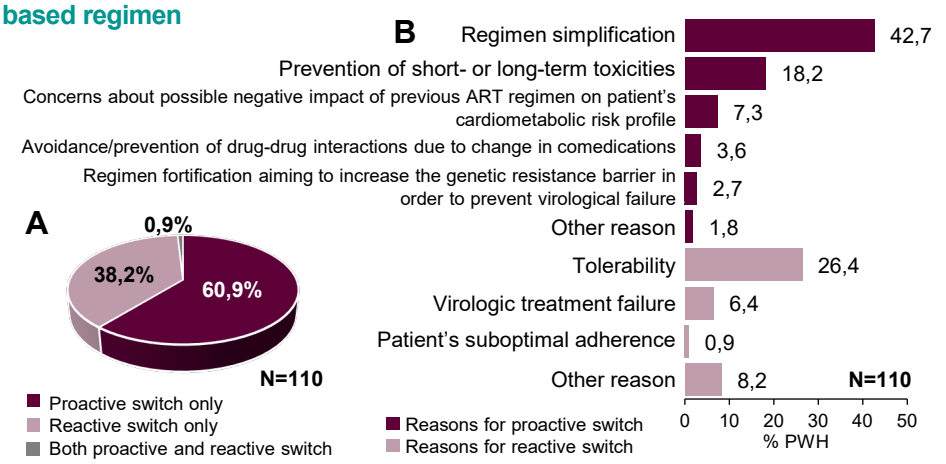
[a]without AIDS-defining conditions; [b]Defined as HIV-load <50 copies/mL for at least 6 months prior to 1st DOR prescription; [c]among evaluable PWH; [d]≥2 clinically significant medical conditions (excluding infections/infestations); [e]Age of the two PWH was 53.0 and 88.0; [f]CD4+ absolute count of the two PWH was 440.6 and 943.3 cells/mm^3.

- Median CCI score in the overall population was 1.0 (IQR: 0.0-2.0);
  - most common (≥10%): dyslipidaemia (30.9%) and hypertension (12.7%)
- 45.5% of PWH were receiving comedications for the treatment of comorbidities;
  - most common (≥5%): lipid-lowering drugs (24.5%), antihypertensives/heart failure agents (10.9%), antidepressants/anxiolytics and antithrombotics (7.3%, each).

Reasons for switch

- 60.9% of PWH were proactively switched to a DOR-based regimen, with most common reason being 'regimen simplification' (42.7%) (Figure 2).

Figure 2. (A) Types and (B) reasons for switch from a prior ART to a DOR-based regimen



Conclusions

- Real-world data from the DORAVITO study provide insight into the current prescription landscape of DOR in Greece, revealing that switching to a DOR-based regimen is a valuable option for PWH who require ART simplification, increased tolerability and avoidance of drug toxicities.

Abbreviations

3TC, Lamivudine; AIDS, acquired immunodeficiency syndrome; ART, antiretroviral therapy; ARV, antiretroviral; CCI, Charlson comorbidity index; DOR, doravirine; FDC, fixed-dose combination; HIV, human immunodeficiency virus; HBV, hepatitis B; HCV, hepatitis C; INSTI, integrase strand transfer inhibitor; IQR, interquartile range; L, line (of treatment); N, number of PWH; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; PWH, people with HIV; SA, single agent; SD, standard deviation; TDF, Tenofovir Disoproxil Fumarate.

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