One year of follow-up after switching to doravirine in treatment-experienced people living with HIV: a real-world cohort study

Vincent Lanting[1], Piter Oosterhof[2], Daoud Ait Moha[1], Roos van Heerde[1], Marie José Kleene[1], Janneke Stalenhoef[1], Marieke de Regt[1], Saskia Vrouenraets[1], Guido van den Berk[1], Kees Brinkman[1]

1. Department of Internal Medicine, OLVG, Amsterdam, Netherlands; 2. Department of Clinical Pharmacology, OLVG Hospital, Amsterdam, Netherlands

Background

Doravirine is a non-nucleoside reversed transcriptase inhibitor with demonstrated effect as third agent in treatment naive and experienced people living with HIV (PLWH). Real world data studies are scarcely available. In the OLVG hospital, patients were switched to a doravirine based regimen in order to reduce medication costs. Patients only switched in absence of a NRTI or NNRTI mutation.

Aim

To evaluate efficacy and tolerability of a doravirine based regimen in treatment experienced patients.

Methods

Retrospective cohort study

Cohort:

- All treatment experienced PLWH
- Virologically suppressed
- Switched to doravirine based regimens
- At least 1 year of follow-up

Primary outcomes:

- Continued doravirine after 1 year
- Reasons to stop

Secondary outcomes

- Change in laboratory measurements and BMI
- Differences in costs compared to prior CART

Data is collected by using the Dutch national HIV registry.

Results

From September 2019 until June 2020, 687 PLWH switched to a doravirine based regimen (97.7% DOR/3TC/TDF). The cohort existed of 92% men and the mean age was 49.1 (±11.1) years. The mean time between HIV diagnosis and switch to doravirine was 12.3 (±7.9) years. All PLWH switched from 36 different cART regimens. The majority (60.6%) switched from EVG/c/FTC/TAF (23.2%), RPV/FTC/TAF (22.4%), or BIC/FTC/TAF (15.0%). After one year 86.3% continued a doravirine based regimen. Within the PLWH that continued treatment, medication costs decreased from €4,553,716 to €3,470,974 (23.8% reduction) during one year of follow-up.

Reasons to stop a doravirine based regimen

Patients with one-year of follow-up	n=687	Percent.
Continued after one year	593	86.3%
Stopped within one year	94	13.7%
Reasons to stop		
Virologic failure	4	0.6%
Resistance - V106A	1	0.1%
Incompliance	1	0.1%
Unknown	2	0.3%
Toxicity - Medical reason	11	1.6%
Increased ALT levels	6	0.9%
Decreased renal function	3	0.4%
Preventive after diagnosis of osteoporosis	2	0.3%
Toxicity - Patient-reported adverse event*	70	10.2%
Insomnia	17	2.5%
Psychological symptoms	17	2.5%
Gastro-intestinal	20	2.9%
Musculoskeletal	11	1.6%
Possible allergic skin reactions	8	1.2%
Other skin reactions	6	0.9%
Other	8	1.2%

* First row demonstrates the total number of patients followed by the categories of adverse events. Some patients had more than one adverse event as reason to stop.

Laboratory measurements and BMI for PLWH that continued doravirine after one year

For the first 335 patients, laboratory and BMI (if available) data was collected. 280 patients continued doravirine after one year of follow-up and were included in the analysis.

Measurement	Number of paired measurements (n=280) [1]	Baseline	Follow-up	p=
Viral load <50	174 (62.1%)	170 (97.7%)	170 (97.7%)	1.00
Viral load <100	174 (62.1%)	174 (100%)	172 (98.9%)	1.00
ALT grade 1-4[2]	254 (90.7%)	21 (8.3%)	26 (10.2%)	0.47
ALT grade 2-4[2]	254 (90.7%)	2 (0.8%)	2 (0.8%)	1.00
eGFR	117 (41.8%)	80 (IQR 71-88)	81 (IQR 72-87)	0.72
HDL-c	167 (59.6%)	1.33 (±0.40)	1.19 (±.29)	<0.01
LDL-c	166 (59.3%)	3.26 (±1.07)	2.88 (±0.84)	<0.01
BMI	38 (13.6%)	26.08 (±3.89)	25.62 (±4.27)	0.51

1 Number of PLWH from whom laboratory data was available at baseline and 1 year of follow-up
2 Increase in ALT levels defined by DAIDS

Conclusions

The large majority of patients successfully continued a doravirine based regimen after one year of follow-up, demonstrating its effective, well tolerated and cost-saving role in maintenance therapy.