

Abstract P-15 Table 2 Features of 29 patients with and without major DRMs to any ART class who have started a DOR-based regimen during the study period

| Patient | Type of DOR-based regimen | DRMs to NNRTIs | Sex | Age, years | AIDS diagnosis | Number of previous ART regimens | Last ART regimen before DOR | History of virological failure | Undetectable at switch | Reason for switching to DOR |
|---------|---------------------------|----------------------------|--------|------------|----------------|---------------------------------|-----------------------------|--------------------------------|------------------------|--------------------------------------|
| 1 | DOR + RAL | E188A | Male | 59 | Yes | 4 | ATV/RTV + DTG | Yes | Yes | Intolerance (chronic kidney failure) |
| 2 | DOR + DTG | K103N, Y181C | Male | 80 | Yes | 5 | DRV + DTG | Yes | Yes | Adverse Events |
| 3 | TDF/3TC/DOR | E188A | Male | 64 | Yes | 6 | TAF/FTC/DRV/cobv | Yes | Yes | Proactive switch (dyslipidemia) |
| 4 | TDF/3TC/DOR | E188G | Female | 62 | Yes | Not available | DRV/RTV | Yes | Yes | Adverse Events |
| 5 | TDF/3TC/DOR | E188A | Male | 44 | No | 6 | TAF/FTC/DRV/cobv | No | Yes | Adverse Events |
| 6 | DOR + DTG | E188A | Male | 63 | No | 2 | TAF/FTC/BIC | Yes | No | Virological failure |
| 7 | TDF/3TC/DOR | E188A | Male | 33 | Yes | 4 | TAF/FTC/BIC | No | Yes | Adverse Events |
| 8 | TDF/3TC/DOR | E188A | Male | 68 | No | Not available | DRV + RTV | No | Yes | Adverse Events |
| 9 | DOR + DTG | L100L, K103N | Male | 58 | No | Not available | DRV + RTV | Yes | Yes | Simplification |
| 10 | TDF/3TC/DOR | E188A | Male | 64 | No | Not available | TAF/FTC/FPV | No | Yes | Adverse Events |
| 11 | TDF/3TC/DOR | E188A | Male | 38 | No | 2 | TAF/FTC/BIC | No | Yes | Proactive switch (dyslipidemia) |
| 12 | TDF/3TC/DOR | K103N, V108L, P225H, Y318F | Male | 49 | No | 3 | TDF/FTC/EFV | Yes | No | Virological failure |

DOR: Doravirine; INI: Integrase Strand Transfer Inhibitors; RAL: Raltegravir; DTG: Dolutegravir; ETV: Etravirine; RPV: Rilpivirine; TAF/FTC: Tenofovir alafenamide; DRV/r: Darunavir/ritonavir; DRV/cobv: Darunavir/cobicistat; 3TC: Lamivudine; MVC: Maraviroc; ABC: Abacavir; EFV: Efavirenz; ART: Antiretroviral Therapy; GRT: Genotypic Resistance Test; DRMs: Drug Resistance Mutations

Materials and Methods Retrospective data of all >18 years old PLWH who initiated a DOR-based antiretroviral treatment (ART) at the Infectious Diseases Clinic of A.O.U.C. Policlinico in Bari between January 1, 2021, and February 15, 2024, having a genotypic resistance test (GRT) archived in the clinic's database were collected. Viral sequences were analyzed using the HIV Sequencing Program of the Stanford HIV Resistance Database to obtain an updated profile of DRMs towards modern drug classes. Differences in immunovirological values, disease history, and ART were evaluated and compared between patients with and without major DRMs in the GRT using Chi-square test and Mann-Whitney U-test.

Results During the study period, 196 PLWH initiated a DOR-based ART. Among them, 131, mostly ART-experienced (120/131, 91%), had available viral genotype data. Of these, 29 subjects (22%) harbored at least one major DRM: 15 towards NRTIs, 10 towards PIs, 1 towards INSTIs, and 12 towards NNRTIs. Additionally, 12 PLWH (41%) showed resistance to two or more classes of antiretroviral drugs. Detailed characteristics of this latter group are reported in table 1. PLWH with evidence of DRMs had a longer history of HIV infection (median 26 vs 13 years, $p < 0.001$) and ART therapy (median 20 vs 11 years, $p < 0.001$), and a greater number of previous ART regimens (median 6 vs 4, $p < 0.001$), compared to the group who did not (table 2). In this group of patients, DOR mainly represented a switching strategy (27/29, 93%), motivated in half of the cases by reported adverse effects to previous ART and in only 3/29 by virological rebound. Notably, a history of previous virological failure was reported in 17/29 subjects (57%), significantly more often than in the other group (16 patients, 16%, $p = 0.008$). DOR was frequently prescribed as a single agent (15/29 patients), often in combination with an INSTI (10/15 patients). At a mean follow-up of 17 (8–35) months from the start of DOR, 25/27 patients had remained on treatment, all with evidence of virological

suppression, without significant differences compared to the DRMs-free group.

Conclusions The unique resistance profile of DOR within the NNRTI class enables its use also in patients with complex HIV infection histories and DRMs. Our real-life data demonstrate that DOR, particularly as single agent, represents a valid option to overcome intolerance or ineffectiveness issues with prior regimens while maintaining virological suppression.

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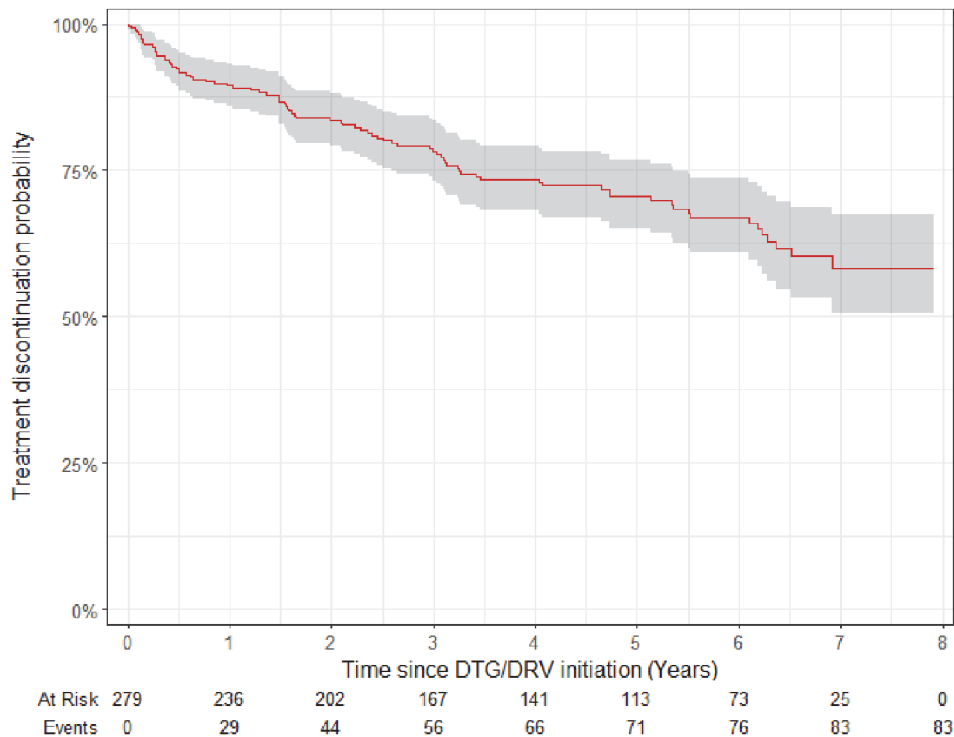
LONG-TERM DURABILITY OF DOLUTEGRAVIR + DARUNAVIR/COBICISTAT DUAL REGIMEN IN HIGHLY ANTIRETROVIRAL-EXPERIENCED PEOPLE LIVING WITH HIV (DODACO STUDY)

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10.1136/sextrans-ICAR-2024.142

Background Dolutegravir (DTG) plus darunavir-cobicistat (DRV-c) dual regimen has been used as a simplified salvage option in treatment-experienced people living with HIV (PLWH), with history of virological failures and multiple class resistance. However, long term data on this combination are missing. We report on the durability of this dual regimen assessed by treatment failure (TF) over time as a composite endpoint.

Material and Methods Retrospective, observational, multicenter study (6 Italian centres). PLWH who started DTG+DRV-c (DTG bid was allowed) since 2015 were included, regardless



Abstract P-16 Figure 1

of HIV RNA levels. Resistance-associated mutations (RAMs) were interpreted according to the Stanford HIVdb mutation list. The primary endpoint was the TF defined as any reason of discontinuation, including virological failure (VF) (i.e. confirmed HIV RNA ≥ 50 copies/mL or any detectable viral load followed by followed by any treatment switch). Survival analysis with Kaplan-Meier estimator was used to assess the probability of treatment discontinuation over time. Multiple logistic regression was used to estimate the probability of TF at 1 year following the initiation of DTG+DRV-c.

Results 283 patients were included (66.4% males, median age 60 years, median nadir CD4 + T-cell 153 cells/ml, 36% with previous AIDS events). The median duration of therapy was 24 years, 45% of people experienced 8 or more previous treatment lines. Participants had a median follow-up of 4 years since DTG+DRV-c initiation. At the baseline, (i.e. DTG +DRV-c initiation), only 57.7% and 67% individuals had CD4+T-cell count >500 cells/ml and HIV RNA < 50 c/ml, respectively. Primary RAMs for NRTI, NNRTI, PI and INI were documented in 86, 71, 37 and 15%, respectively. Only 2 patients were on DTG bid. Treatment discontinuation (TD) occurred in most cases for to simplification, toxicity, intolerance, drug interaction (42 cases, 14.8%), while VF occurred in only 7 persons (2.5%). Death and loss-to-follow up occurred in 18 and 8 subjects. The probability of TD was 11%, 16%, 22%, 27%, 29%, 33%, and 42% after 1, 2, 3, 4, 5, 6 and 7 years of treatment, respectively (figure 1). At multiple logistic regression, after adjusting for age, sex, viral load at baseline and number of lines of therapy, the only factor associated with a reduced probability of TF after 1 year of treatment was an increase in CD4+T cell count of 50-unit from the baseline value (OR=0.947, 95%CI 0.9–0.992).

Conclusions DTG+DRV-c is an effective and durable dual combination in highly treatment-experienced PLWH. Most

reasons of discontinuation were other than VF (mainly age-related phenomena, such as drug-interactions), confirming its efficacy as simplified and salvage therapy in PLWH with multiple class resistance.

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INSIGHTS INTO PATIENTS PERSPECTIVES: IDENTIFYING BARRIERS IN THE TRANSITION FROM ORAL TO INJECTABLE ANTIRETROVIRAL TREATMENT

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10.1136/sextrans-ICAR-2024.143

Background The introduction of long-acting injectable antiretroviral treatment (LA ART) in Italian Infectious Diseases Centers has marked a cornerstone in the management of HIV infection. However, despite the enthusiastic reception of transitioning to LA ART among some People Living with HIV (PLWH), clinical observation has revealed a subset of patients who, despite meeting the inclusion criteria for this treatment, firmly reject its prescription. This study aimed to investigate potential social, cultural, or clinical determinants underlying this phenomenon, to assist clinicians in formulating individualized therapeutic strategies.

Materials and Methods From January 1, 2023, to February 15, 2024, all eligible PLWH followed at the Infectious Diseases Outpatient Clinics of the University Hospitals of Bari and Foggia, were proposed a switch to injectable ART during routine follow-up visits. Reasons for both switch acceptance and refusal were collected through both in-person and