REALITY
Raltegravir Real Life Study

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Real-word characterization of the Portuguese population living with HIV who initiated Raltegravir based-regimen between 2015 and 2017 - REALITY Study

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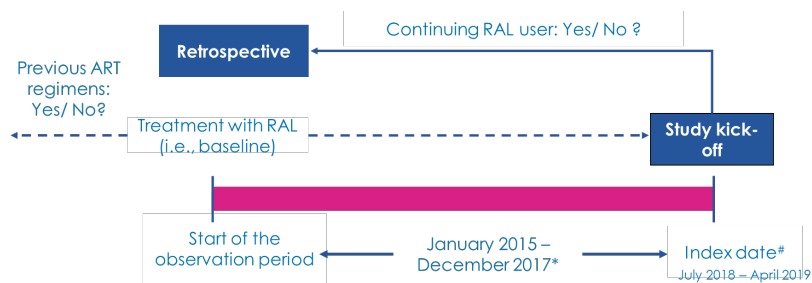
INTRODUCTION

Raltegravir (RAL) was approved as the first integrase inhibitor for the treatment of HIV-1. Although there is a large amount of evidence regarding its effectiveness and safety, there is still a lack of data on the characterization of the Portuguese HIV-1 infected population under RAL therapy.

AIM

This study aimed at characterizing patients, in Portugal, who started RAL therapy between January 2015 and December 2017, and compare those who were under RAL-based therapy (RAL continuing users) *versus* those who discontinued RAL regimens (RAL non-continuing users), at the time of study inclusion (index date).

METHODS

Non-interventional retrospective study including 11 Portuguese centers. Data were collected from clinical files and a patient-reported questionnaire was administered during the inclusion visit, to assess the satisfaction with RAL treatment, only in patients that were under RAL-based regimens, at that time (RAL continuing users). The HIV Treatment Satisfaction Questionnaire, HIVTSQs© (version 8.4.10) has been linguistically validated, including clinician review and pilot testing in Portuguese patients. The HIVTSQs[1], range from 0 to 60 points; the higher the score, the higher the satisfaction with treatment. Study design and data collection scheme are presented in **Figure 1**.

* HIV-infected patients who initiated RAL based-regimens during the study's observation period
# Patient's satisfaction was assessed only in participants who are continuing RAL users, at index date (inclusion date).

Legend: ART, antiretroviral therapy. RAL, raltegravir.

Figure 1. Study design flow chart of the REALITY Study

RESULTS

■ The majority of patients were Portuguese middle-aged men

A total of 302 patients were recruited between July 2018 and April 2019. Patients were mostly males (70.0%), of Portuguese nationality (83.0%) and with a mean age of 49 years. Patient´s were mostly infected via heterosexual transmission (58%). At RAL initiation, the mean value of CD4+ T counts was 530.2 cells/mm^3 and 49% of patients had detectable viral load.
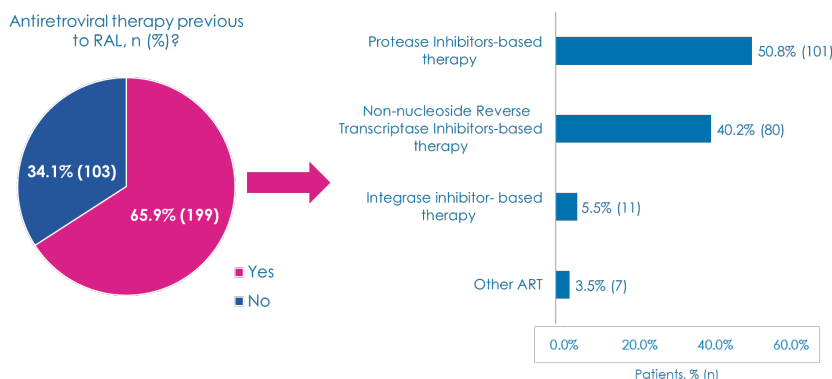

Figure 2. Previous antiretroviral therapy in treatment-experienced patients

■ Approximately half of the patients received one or more previous ART

At baseline (RAL start date), 34.1% of the patients were treatment-naïve whereas 65.9% were treatment experienced. The most frequent previous ART regimens were protease inhibitors (50.8%) and non-nucleoside reverse transcriptase inhibitors (40.2%) - **Figure 2**. Around half of the treatment-experienced patients (52.3%) received up to two (median) antiretroviral treatments before RAL.

■ Comorbidities at baseline

At baseline, 53.3% of patients had non-AIDS related comorbidities (NARC), with a median number of two. The most frequent comorbidities were hypercholesterolemia (44.1%), arterial hypertension (42.2%), diabetes *mellitus* and depression (each with17.4%). Approximately 17% of patients were co-infected with HCV and/or HBV (**Figure 3**).

■ Higher burden of comorbidities in RAL continuing patients

RAL continuing users were compared with patients who discontinued RAL, at inclusion visit. The proportion of patients with any NARC at baseline was higher for RAL continuing users compared to RAL non-continuing patients (56.6% vs 39.7%, p=0.0204). No statistically significant differences were observed between both subgroups regarding the prevalence of each comorbidity. Both subgroups of patients showed a median number of comorbidities of two.
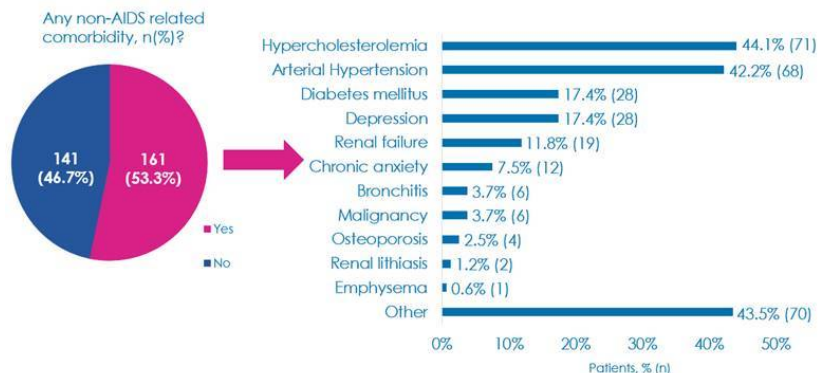

Figure 3. Non-AIDS-related comorbidities of study participants at baseline.
Note: Baseline was defined as the time of initiation of RAL-based therapy. The number and type of non-AIDS-related comorbidities were calculated based on the number of patients with at least one reported non-AIDS-related comorbidity (n=161 patients).

■ Most patients were RAL continuing users at index date

At study inclusion, 80.8% (n=244) of patients were RAL continuing users. The median duration of RAL treatment was 2.1 years.

■ The majority of patients improved their virological and immunological parameters over time

No statistically significant differences were observed between RAL continuing users vs RAL non-continuing users regarding median values of CD4+ T' lymphocyte counts and viral load at baseline.
At last measurement, 97.5% (n=238) of RAL continuing users were suppressed. Within these patients, when comparing the RAL treatment-naïve group versus the RAL treatment-experienced group, 96.3% (n=78) and 98.2% (n=160) were suppressed, respectively.
Among RAL continuing users an improvement of CD4+ T counts were observed with 68.4% having >500 cells/mm^3 at last measurement, while only 48.8% had at baseline.

■ Patient´s on RAL-based therapy reported high treatment satisfaction
The average global satisfaction score was 55.4 points (minimum=2, maximum=60), for patients on RAL-based regimens, evaluated at inclusion visit.

CONCLUSIONS

REALITY study demonstrates that RAL-based regimens are a clinical choice for a heterogeneous population including those with previous ART experience and with a high burden of comorbidities.

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