Reasons for choosing darunavir/ritonavir 600/100 mg twice daily vs. 800/100 mg once daily in treatment-naïve patients: 10 years data from the ICONA cohort

A. Tavelli1, M. Palma2, S. Lo Caputo3, G. Maddeddu4, P. Bonfantii, B. Menzaghi5, S. Nozza7, A. Antinori6, R. Termini2, A. d’Arminio Monforte4 for ICONA Foundation Study Group

1 ICONA Foundation, Milan, Italy; 2 Janssen-Cilag SpA, Cologno Monzese, Italy; 3 Policlinico di Bari, Bari, Italy; 4 University of Sassari, Sassari, Italy; 5 ASST di Lecco, A. Manzoni Hospital, Lecco, Italy; 6 ASST della Valle Omona, Busto Arsizio Hospital, Busto Arsizio, Italy; 7 San Raffaele Scientific Institute, Milan, Italy; 8 INMI “L. Spallanzani” IRCCS, Rome, Italy; 9 ASST Sant Paolo e Carlo, University of Milan, Milan, Italy; *alessandro.tavelli@foriconacono.org

**Introduction/Summary**

Darunavir/ritonavir (DRV/r) is indicated as first-line option in persons with low adherence or before the results of the resistance test, due to the high genetic barrier and potency.

DRV/r 600/100 mg twice daily (BID), is licensed for ART-experienced patients, while for ART-naïve patients the recommended dose is 800/100 mg once daily (QD).

However, in clinical practice, a non negligible proportion of ART-naïve subjects are given DRV r/BID.

**Aim**

The aim of this analysis is to identify patterns of use of DRV/r BID, by analyzing predictors of DRV/r BID vs DRV QD start as first-line treatment.

**Study Design and Methods**


Starting their first cART with DRV/r were 82% male, median age (IQR) 40 years (32-48), 80% Italian, 19% with diagnosis of AIDS CD4 count 256 cells/mmc (85-412), 32-48), 80% Italian, 19% with diagnosis of AIDS CD4 count 256 cells/mmc (85-412), 32-48), 80% Italian, 19% with diagnosis of AIDS CD4 count 256 cells/mmc (85-412), 32-48), 80% Italian, 19% with diagnosis of AIDS CD4 count 256 cells/mmc (85-412), 32-48), 80% Italian, 19% with diagnosis of AIDS CD4 count 256 cells/mmc (85-412), 32-48), 80% Italian, 19% with diagnosis of AIDS CD4 count 256 cells/mmc (85-412), 32-48), 80% Italian, 19% with diagnosis of AIDS CD4 count 256 cells/mmc (85-412), 32-48), 80% Italian, 19% with diagnosis of AIDS CD4 count 256 cells/mmc (85-412).

**Results**

A total of 1503 ART-naive subjects starting their first CART with DRV/r were included: 1297 subjects started DRV/r BID (86.3%) and 206 DRV/r BID (13.7%).

**Patients’ characteristics**

82% male, median age (IQR) 40 years (32-48), 80% Italian, 19% with diagnosis of AIDS CD4 count 256 cells/mmc (85-412), HIV-RNA 5.1 log10 copies/mL (4.5-6.6), other participants’ characteristics at the start of DRV/r are shown in Table 1.

**ARV regimens**

80.4% started DRV/r in a triple therapy, 5.6% in dual regimen (81% with RAL and 13% with MRV), with a higher proportion of patients with >3 drugs in the DRV/r BID group (22.3% vs 12.6%, p=0.002). 80% starting with TDF/FTC as NRTI backbone, 10.8% with ABC/3TC and 1.1% with AZT/3TC

There was a peak in the use of DRV/r in 2012-2013 (p<0.001) [Figure]

Figure – Proportion of DRV/r use by frequency (QD vs. BID) according to calendar period

**Predictors of DRV/r BID start**

Fitting a logistic regression model, after controlling for potential confounders, older patients, subjects with CD4<400/mm, patients given regimens >3 ARV drugs, patients from centers of southern Italy and patients treated in 2012-2013 showed a significantly higher probability of starting DRV/r BID. A decreased probability of DRV/r BID start was observed in patients with AIDS diagnosis [Table 2]. There was evidence that the use of regimens with >3 ARV was greater in people with HIV RNA>500,000 copies/mL than in those with HIV RNA≤500,000 copies/mL (OR=5.9; p<0.001)

**Table 2 – crude odds ratio (OR) and adjusted odds ratio (AOR) of starting DRV/r BID**

**Conclusion**

Italian clinicians allocate DRV/r BID as first line regimen in several scenarios: elderly subjects, severely immunodepressed, highly viremic patients; more frequently in combination than more than 3 drugs and in patients treated in 2012-2013.

Subjects with AIDS are mostly given DRV/r BID probably due to the concomitant medications for opportunistic infections.

**Funding**

This analysis is supported by Janssen Italy.

**ICONA Foundation is supported by unrestricted grants from BMS, Gilead, Janssen, MSD and ViV HealthCare**

**CONTACT**

M Andreaoni, A Antinori, A Castagna, F Bai, MC Moioli, R Piolini, AL Ridolfo, S Salpietro, C Tincati, (Milano); P. Bonfanti (Bologna); A. Lazzarin, G. Rizzardini, M Puoti, A Castagna, F Bai, MC Moioli, R Piolini, AL Ridolfo, S Salpietro, C Tincati, (Milano)