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Antiretroviral Treatment in PLWH with late Diagnosis initiating ART with DTG/3TC or BIC/TAF/FTC: a real-world cohort analysis

Gundolf Schuettfort[1], Alfonso Cabello[2], Maria Crusells[3], Miguel Górgolas[2], Carmen Hidalgo Tenorio[4], Juan Lopez[5], Rafael Mican[6], Eugenia Negredo[7], Sebastian Noe[8], Jordi Puig[7], Federico Pulido[9], Jürgen Rockstroh[10], Sergio Rodriguez[11], Rosario Serrao[12], Christoph Stephan[1], Miguel Torralba[13], Diva Trigo[14], Maria Vivancos[15], Annette Haberl[1]

[1]University Hospital Frankfurt, Frankfurt / Germany, [2]Hospital Universitario Fundacion Jimenez Diaz, Madrid / Spain, [3]Hospital Clínico Universitario Lozano Blesa, Zaragoza / Spain, [4]Universitario Virgen de las Nieves, Granada / Spain, [5]Hospital Universitario Gregorio Maranon, Madrid / Spain, [6]Hospital Universitario La Paz, Madrid / Spain, [7]Hospital Universitario Germans Trias i Pujol, Barcelona / Spain, [8]MVZ am Goetheplatz, München / Germany, [9]Hospital Universitario 12 de Octubre, Madrid / Spain, [10]University Hospital Bonn, Bonn / Germany [11]Hospital Universitario Getafe, Madrid / Spain, [12]Centro Hospitalar de Sao Joao, Sao Joao / Portugal, [13]Hospital Universitario Guadalajara, Guadalajara / Spain, [14]Hospital Professor Doutor Fernando Fonseca, Lisbon / Portugal, [15]Hospital Universitario Ramon y Cajal, Madrid / Spain

Objectives

- Active opportunistic infections and/or low CD4+T-cell (CD4+) counts are exclusion criteria in most clinical trials. People living with HIV (PLWH) and late diagnosis are therefore inadequately represented in studies assessing efficacy of antiretroviral treatment (ART) regimens.
- Given the consecutive lack of data from clinical trials, real-world data is of high importance in this vulnerable subset of PLWH. There are currently no data from European studies solely focusing on virologic outcomes in treatment naïve PLWH with baseline CD4 count ≤ 200/µl comparing dolutegravir/lamivudin (DTG/3TC) and bictegravir/tenofovir alafenamid/emtricitabine (BIC/TAF/FTC).
- Aim of the presented study was to obtain information on the effectiveness and tolerability/safety of DTG/3TC in treatment naive PLHIV with a CD4 cell count ≤ 200/µl. Results were compared with data from treatment naive patients with a CD4cell count <200/µl treated with BIC/TAF/FTC.

Methods

- We conducted a retrospective, multicentre, multinational study with 15 investigational sites in Germany, Spain and Portugal. Primary objective was effectiveness of initial ART with DTG/3TC compared to BIC/TAF/FTC in patients with low CD4 counts at baseline (<200/µl). Primary endpoint was proportion of PLWH with <50 copies/ml treated with DTG/3TC and BIC/TAF/FTC after 48 weeks after treatment initiation.
- All PLWH with CD4<200/µl and/or an AIDS defining disease who started first line ART with DTG/3TC or BIC/TAF/FTC between July 2019 and September 2022 were included in this study. Virologic response was analyzed using FDA snapshot analysis (HIV-1 RNA <50 copies/ml at week 48).

Results

- A total of 259 PLWH were included in the study. 69 PLWH were started on 2DR DTG/3TC and 190 on 3DR BIC/TAF/FTC. After matching 1 to 1 (matching criteria: Age, gender, CD4, HI-Viral load, CDC stadium), mean baseline CD4 count was 98/µL (SD 43) and 24.6% presented with CDC C3 status.
- 97.1% and 94.2% of PLWH on 2DR and 3DR, respectively, had a viral load <50 copies/ml at week 48. Discontinuation rates were 5.8% in the 2DR and 7.2% in the 3DR group. Between-group differences are presented in table 1.

Conclusions

- In a European cohort of PLWH and late diagnosis starting first line ART with DTG/3TC or BIC/TAF/FTC, there were no significant differences in discontinuation rates or virologic response rates at week 48.
- Our results indicate that the choice between ART 2DR and ART 3DR can be made on an individual basis of the patient presenting late for first line ART. Future research will focus on the identifying factors associated with regimen selection in this cohort.

Parameter	Overall (n=138)	2DR DTG/3TC (n=69)	3DR BIC/TAF/FTC (n=69)	*P*
Age (years; mean ±SD)	42.5 ± 12.5	42.1 ± 9.6	43.8 ± 10.8	0,963
Sex (% male/ female)	92.8 / 7.2	92.8 / 7.2	92.8 / 7.2	/
AIDS-defining condition (n/%)	34 / 24.6	17 / 24.6	17 / 24.6	/
Baseline CD4 / µl (mean ± SD)	98 ± 83	105 ± 87	97 ± 65	0,531
Baseline HI Viral load (mean copies/ml ± SD)	275320 ± 45600	281730 ± 44600	230400 ± 66800	0,428
Discontinuation of ART at week 48 (n / %)	9 / 6.5	4 / 5.8	5 / 7.2	0,481
Adverse events at week 48 (n / %)	9 / 6.5	4 / 5.8	5 / 7.2	0,481
HIV VL<50 copies/ml at week 48 (n / %)	132 / 95.6	67 / 97.1	65 / 94.2	0,206

Table 1: Baseline characteristics and outcomes at week 48.

* Correspondence: gundolf.schuettfort@med.uni-frankfurt.de