Poster-Board #: **0495**

DISCONTINUATIONS & VIROLOGIC RESPONSE IN LATE PRESENTERS WITH INSTI- OR PI-BASED ART

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CROI Conference on Retroviruses and Opportunistic Infections

March 4-7, 2019
Seattle, Washington

Objectives

- Active opportunistic infections and/or low CD4+T-cell (CD4+) count are exclusion criteria in most clinical trials. Therefore late presenters (LP) are inadequately represented in studies comparing efficacy of antiretroviral regimens. This results in a lack of data on optimal treatment options for this special population.
- Our study aims to investigate the efficacy and safety of first line ART with integrase-inhibitor (INSTI) or protease-inhibitor (PI) based regimens in patients with low CD4+-counts and/or AIDS-defining disease.

Methods

- We conducted a retrospective, multicenter study to investigate discontinuation rates and clinical outcome in starting first line ART in patients with a CD4+T-cell count <200/µL and/or AIDS defining disease. Data were collected in three European HIV clinics: University Hospital Frankfurt, Kings College London and Hospital Fundación Jiménez Díaz Madrid.
- All patients with CD4+T-cell count <200/µL and/or AIDS defining disease who started an INSTI or PI-based first line ART between January 2014 and December 2016 were included in this analysis. Proportions of discontinuations and/or adverse events were compared using univariate analysis. Virologic response rates were analyzed by using FDA snapshot analysis (HIV-1 RNA <50 copies/mL at week 48).

Table 1:

Variable	Integrase Inhibitors (n = 131)	Protease Inhibitors (n = 87)	P
Age (years; mean ± SD)	43 ± 15.5	53 ± 16.7	**0.016**
Sex (% male/female)	84.7 / 15.3	88.5 / 11.5	0.429
n / % of non-European origin	26 / 19.8	26 / 29.9	0.192
CD4 /µL (mean ± SD; baseline)	103 ± 137	90 ± 109	0.144
CD4 / CD8 ratio (mean ± SD; baseline)	0.12 ± 0.16	0.10 ± 0.18	0.309
CD4 /µL (mean ± SD; week 48)	360 ± 205	315 ± 216	0.412
CD4 / CD8 Ratio (mean ± SD; week 48)	0.33 ± 0.17	0.31 ± 0.20	0.679
Viral load (mean copies/mL ± SD; baseline)	329200 / 10910	115700 / 33980	0.665
Viral load < 50 copies n / % at week 48	113 / 86.2	71 / 81.3	0.444
Mortality (n / %; week 12)	1 / 0.8	2 / 2.3	0.341
Mortality (n / %; week 48)	3 / 2.29	3 / 3.44	0.679
Discontinuation at week 12 (n / %)	23 / 17.6	14 / 16.1	0.778
AE`s* at week 12 (n / %)	28 / 21.3	21 / 24.1	0.593
Discontinuation due to AE at week 12 (n / %)	8 / 6.2	6 / 7.1	0.816
Discontinuation at week 48 (n / %)	41 / 32.0	32 / 36.8	0.471
Virologic failure at week 48 (n / %)*	11 / 8.2	7 / 7.6	0.883
AE`s* at week 48 (n / %)	11 / 8.3	13 / 14.6	0.205
Most frequent AE (gastrointestinal) at week 48	10 / 7.7	6 / 7.4	0.838
Discontinuation due to AE at week 48 (n / %)	4 / 3.4	7 / 8.1	0.097

Results

- A total of 218 late presenters were included in the study; 13.8% women, 23.8% of Non-European ethnicity. Mean (SD) baseline CD4+T-cell count 91/µL (112) and CD4/CD8 ratio of 0.11 (0.19). 131 patients started on INSTI-based regimen and 87 on PI`s respectively. Between-group differences are presented in table 1.
- Patients starting on PI-based regimen were more likely to be older (mean age 53yrs vs. 43yrs.).
- 91.8% in the INSTI and 92.4% in the PI group achieved a viral load <50 copies/mL at week 48.
- Discontinuation rates due to adverse events were 3.4% in the INSTI and 8.1% in the PI group respectively.
- Most frequent adverse events in the INSTI as well as in the PI group were gastrointestinal symptoms (17.2% vs. 14%) followed by nausea (5.2% vs. 6.0%).
- No significant differences in discontinuation rates were observed at week 12 and 48 between INSTI and PI-based regimens (p=0.78 and 0.47 respectively).
- There was no difference in virologic response rates between the INSTI and PI group (91.8% vs. 92.4%; p = 0.88; odds ratio (95% CI) 1.05 (0.38– 2.82).

Conclusions

- In a European cohort of late presenters starting first line ART with INSTI or PI based regimens, there were no significant differences in discontinuation rates and virologic response at week 48. Thus our results indicate that the choice between INSTI and PI 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.

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