Effectiveness and safety of D/C/F/TAF in an observational Italian cohort: interim analysis of DIAMANTE (TMC114FD1HTX4011) study

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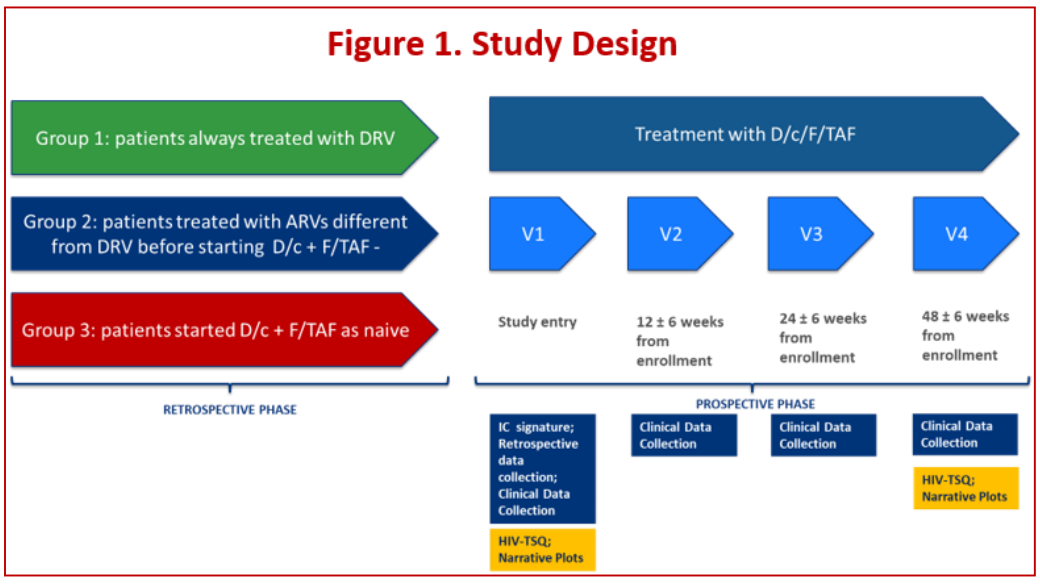
BACKGROUND

To improve adherence to ART, a single-tablet regimen (STR) based on the cobicistat-boosted protease inhibitor darunavir (DRV), together with emitricitabine and tenofovir alafenamide (D/C/F/TAF), has been developed. This formulation reduces the pill burden and mistakes in drug intake.

MATERIALS AND METHODS

DIAMANTE is an Italian, retrospective and prospective observational study carried on HIV-positive adult outpatients treated with D/C/F/TAF in eighteen centers. Three groups of patients have been enrolled: Group 1 always treated with DRV-based ART; Group 2 patients switching to D/C/F/TAF from a non-DRV-based ART and Group 3 patients starting D/C/F/TAF as first-line therapy at least one month before enrollment (Figure 1). Here we show the results of an interim analysis related to the effectiveness and safety of D/C/F/TAF in patients who completed the study in August 2020.

Figure 1. Study Design



RESULTS

Two-hundred-forty-six patients have been enrolled. Of them, 10% (25) were females. At the August 2020 analysis, including 187 patients having completed the study, the virological success was 97% in Group 1, 94% in Group 2 and 97% in Group 3 (Figure 2). It was noticed an improvement in all groups of the immunological outcome, especially in naïve patients who showed a median CD4 cell count increase of 15% at V4. The data are detailed in Table 1.

At August 2020, 32/246 (13%) patients withdrew from the study; 5% for loss to follow up, 2% for stopping D/C/F/TAF-based treatment for any reason; 1% due to pregnancies and 3% for other reasons.

Seventy-four out of 246 (30%) patients reported at least one AE of mild severity (78%); 3 (1%) patients discontinued the study due to AE. Twelve (5%) patients reported SAE, 3 of them discontinued study; one event was considered related to D/C/F/TAF.

Figure 2. Virological Success

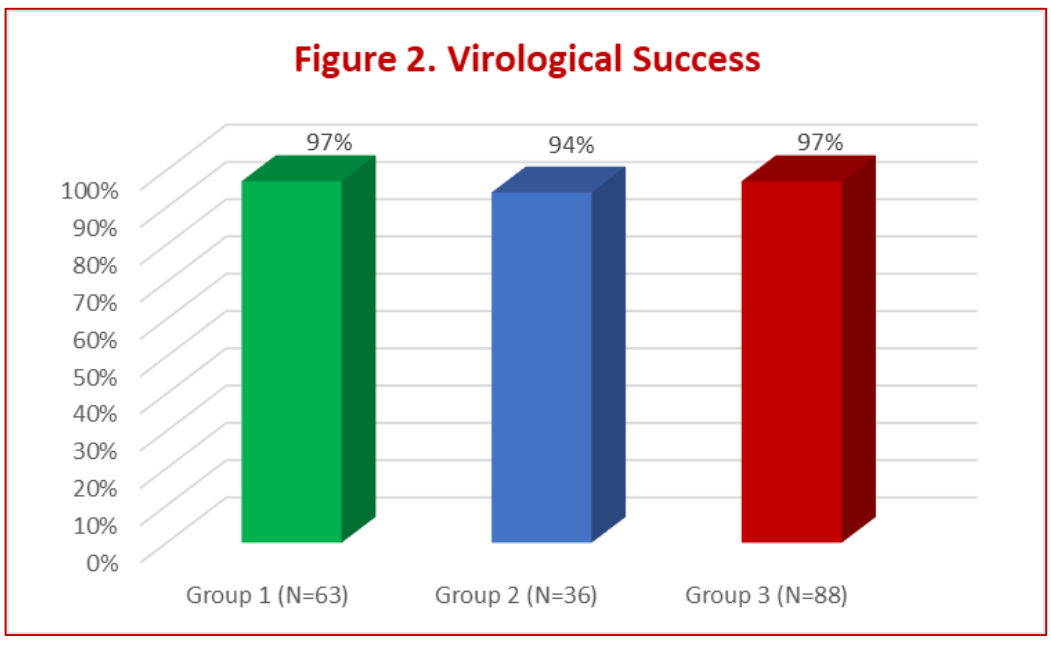


Table 1 - Immunological Parameters stratified by groups

	Group 1	Group 2	Group 3
Median (Q1-Q3) CD4 cell count - Visit 1	697 (487;795) (N=63)	582 (438,5; 780,5) (N=36)	481 (274; 729) (N=87)
Median (Q1-Q3) CD4 cell count - Visit 4	691 (504; 919) (N=61)	646 (463; 806) (N=33)	554 (381; 757) (N=85)
Median CD4/CD8 (Q1-Q3) - Visit 1	0,7 (0,5-0,9) (N=43)	0,7 (0,4-1,1) (N=26)	0,4 (0,2-0,6) (N=55)
Median CD4/CD8 (Q1-Q3) - Visit 4	0,8 (0,6;1,2) (N=60)	0,8 (0,4;1,1) (N=27)	0,7 (0,4;0,9) (N=70)

CONCLUSIONS

In the first 187 patients having completed the DIAMANTE study, the treatment based on D/C/F/TAF has shown to be effective and well-tolerated in clinical practice.

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