The Efficacy and Safety of Dual Versus Triple-Agent Antiretroviral Therapy in HIV-Treatment Naïve Veterans

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Background

- Advances in antiretroviral (ARV) treatments since 1996
- More than 25 ARV drugs from six different classes
- Current treatment guidelines recommend initiating a regimen consisting of three active drugs, generally two nucleoside reverse transcriptase inhibitors (NRTI) plus a third agent from another class for most antiretroviral naïve patients
- The morbidity and mortality of people living with HIV are now mostly driven by long-term non-AIDS complications, including ARV-related toxicities and complications
- Dual-therapy has been suggested to improve CD4/CD8 ratio and may reduce toxicities of antiretroviral therapy
- The durability and long-term safety of these regimens have not been extensively evaluated

Objective

To assess the efficacy and safety of raltegravir plus darunavir/ritonavir compared to tenofovir plus emtricitabine plus darunavir/ritonavir in the HIV-positive treatment-naïve veteran population at 96 weeks using a variety of virologic and immunologic markers

Outcomes

- Primary Outcome: virologic response (viral load less 50 copies/mL)
- Secondary Outcomes: change from baseline in CD4 and CD8 cell counts, CD4/CD8, serum creatinine, and lipid parameters; genotypes of virologic failures before week 96

Methods

- Retrospective Electronic Chart Review
- Setting: Veterans Affairs North Texas Health Care System
- Time Period: October 1, 1994 – September 30, 2018

Statistical Analysis

- Student's T-test (continuous data)
- Chi-Square Test (nominal data)

Patient Selection

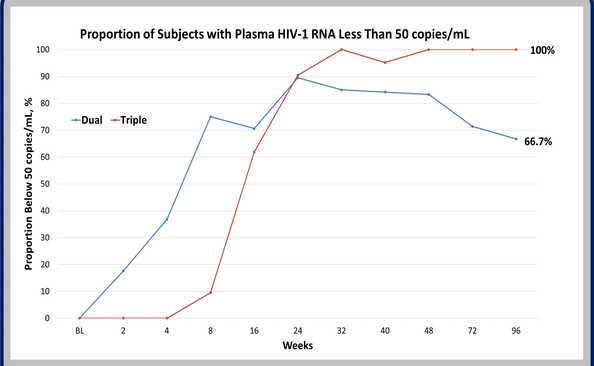
Inclusion Criteria	Exclusion Criteria
Documented HIV-1 diagnosis ARV-treatment naïve Prescribed study drug regimens for at least 96 weeks (DRV/boosted plus RAL or DRV/boosted plus TDF/FTC)	Prescribed any other ARV regimen during time period of interest

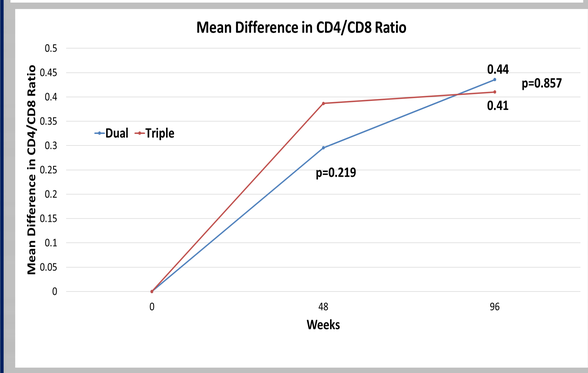
Baseline Characteristics

Characteristic	Dual (n=20)	Triple (n=21)
Age (years), median (IQR)	46 (36-58)	39 (28-54)
Male, n (%)	19 (95.0)	20 (95.2)
Race, n (%)		
African American	9 (45.0)	13 (61.9)
Caucasian	9 (45.0)	5 (23.8)
Positive HCV-AB, n (%)	3 (15.0)	2 (9.5)
Viral load (log), mean ± SD	4.58 ± 0.50	4.81 ± 0.86
CD4 (cells/uL), mean ± SD	299 ± 174	304 ± 174
CD8 (cells/uL), mean ± SD	860 ± 455	910 ± 463
CD4/CD8	0.397	0.393
TC (mg/dL), mean	158.75	139.67
LDL (mg/dL), mean	98.30	83.09
HDL (mg/dL), mean	36.55	33.10
TG (mg/dL), mean	125.05	117.52
SCr (mg/dL), mean	0.94	0.95

Results

	Dual (n=15)	Triple (n=15)	P-value
Primary Outcome			
Viral Load less than 50 copies/mL, n (%)	10 (66.7)	15 (100.0)	0.014
Secondary Outcomes			
Mean change in CD4 (cells/uL) from baseline	+193.93	+251.07	0.376
Mean change in CD8 (cells/uL) from baseline	-37.00	-197.07	0.364
Mean change in CD4/CD8 from baseline	+0.44	+0.41	0.857
Mean change in TC (mg/dL) from baseline	+9.40	+14.81	0.648
Mean change in LDL (mg/dL) from baseline	-1.81	+7.24	0.395
Mean change in HDL (mg/dL) from baseline	+10.00	+10.75	0.889
Mean change in TG (mg/dL) from baseline	+12.87	-14.81	0.358
Mean change in SCr (mg/dL) from baseline	+0.07	+0.12	0.441





Conclusion

- Dual therapy ARV regimen showed similar results regarding immunological response and side effect profile as the standard triple ARV therapy
- Dual therapy ARV regimen in HIV-naïve veterans seems to be virologically inferior to the standard triple ARV therapy

References

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