

Switch to DOR-TDF-3TC vs. Continued Baseline Regimen

DRIVE SHIFT

Switch to Doravirine-TDF-3TC versus Continued Baseline Regimen

DRIVE SHIFT: Design

- **Design:** Open-label, non-inferiority trial in adults with suppressed HIV RNA while taking 2 NRTIs plus anchor drug, randomized (2:1) to immediately switch to fixed-dose doravirine-tenofovir-DF-lamivudine or continue the baseline regimen with delayed switch at 24 weeks
- **Inclusion Criteria**
 - Age ≥ 18 years
 - Suppressed HIV RNA ≥ 6 months
 - No history of virologic failure
- **Baseline Regimen**
 - 2 NRTIs + (boosted protease inhibitor, boosted elvitegravir, or NNRTI)

2x

Immediate Switch
Doravirine-TDF-3TC
(n = 447)

1x

Delayed Switch
**Baseline Regimen to Week 24,
then Doravirine-TDF-3TC**
(n = 223)

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DRIVE SHIFT: Baseline Characteristics

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Characteristic	Immediate Switch (n = 447)	Delayed Switch (n = 223)
Age in years, median (range)	43 (21-71)	42 (22-71)
Male, n (%)	372 (83.2)	194 (87.0)
White, n (%)	344 (77.0)	168 (75.3)
Black or African American, n (%)	56 (12.5)	34 (15.2)
CD4 count (cells/mm ³), median (range),	633 (82-1,928)	625 (140-1,687)
CD4 count <200 cells/mm ³ , n (%)	13 (2.9)	4 (1.8)
Median months on prior regimen (range)	48.4 (7-265)	50.5 (7-181)
Baseline mutations: K103N, Y181C, +/- G190A, n (%)	11 (2.5)	13 (5.8)
HBV and/or HCV coinfection, n (%)	14 (3.1)	9 (4.0)

Source: Johnson M, et al. J Acquir Immun Defic Syndr. 2019;81:463-72.

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DRIVE SHIFT: Baseline Antiretroviral Regimens

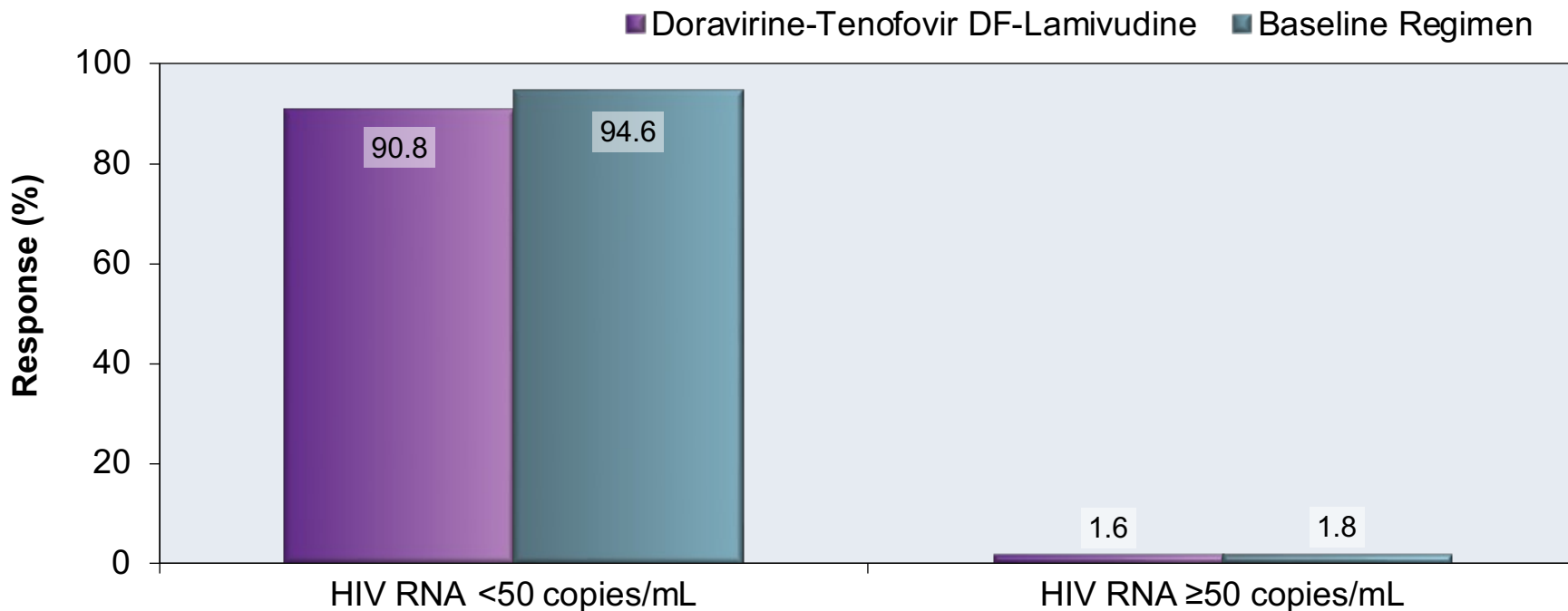
DRIVE SHIFT Baseline Antiretroviral Regimens		
Anchor Agent, n (%)	Immediate Switch (n = 447)	Delayed Switch (n = 223)
Boosted PI	316 (70.7)	156 (70.0)
Darunavir	166 (37.1)	82 (36.8)
Atazanavir	96 (21.5)	43 (19.3)
Lopinavir	54 (12.1)	31 (13.9)
Elvitegravir-cobicistat	25 (5.6)	12 (5.4)
NNRTI	106 (23.7)	55 (24.7)
Efavirenz	78 (17.4)	36 (16.1)
Nevirapine	17 (3.8)	12 (5.4)
Ralpivirine	11 (2.5)	7 (3.1)

*Most common NRTI backbone in both arms: TDF/FTC (73.8% in immediate switch, 69.1% in delayed switch)

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DRIVE SHIFT: Results

Week 48 Doravirine-TDF-3TC vs Week 24 Baseline Regimen (FDA snapshot)

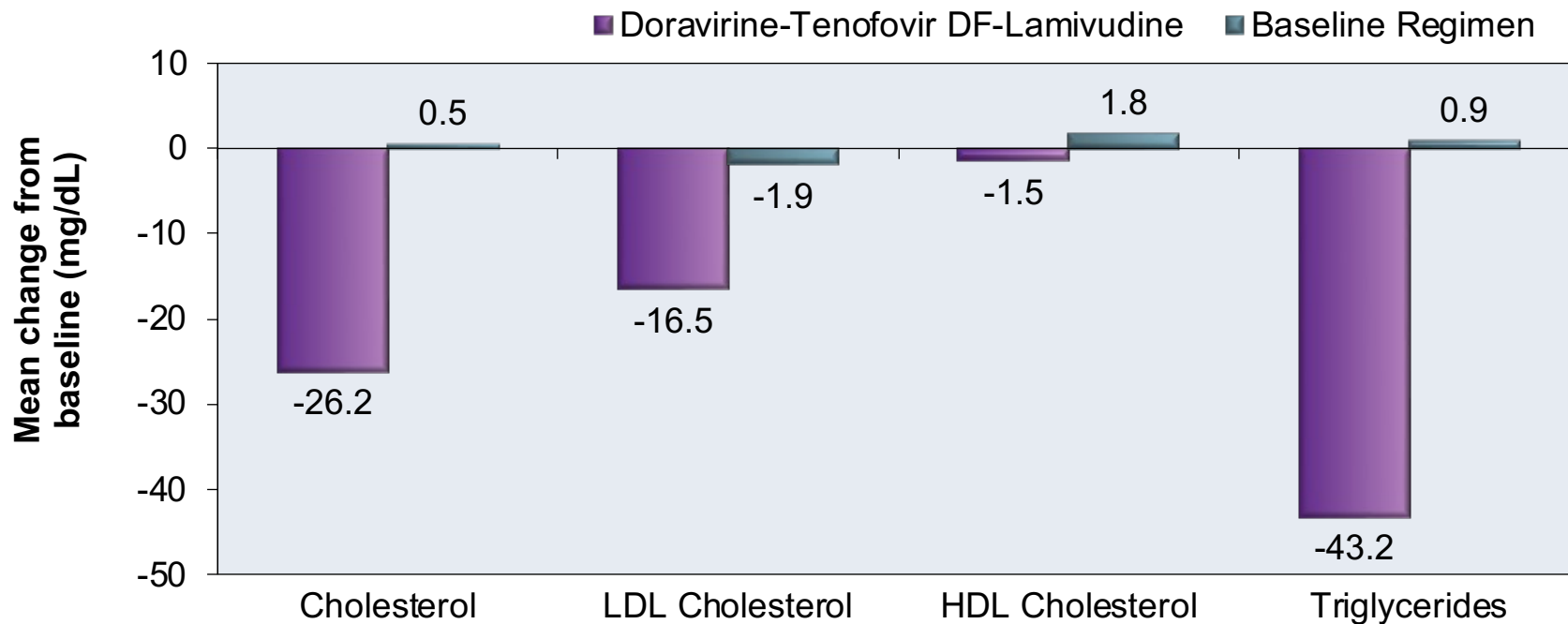


Source: Johnson M, et al. J Acquir Immun Defic Syndr. 2019;81:463-72.

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DRIVE SHIFT: Adverse Effects

Change in Fasting Lipids in Participants Taking a Boosted PI at Baseline



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DRIVE SHIFT: Summary

Conclusions: “Switching to once-daily doravirine-lamivudine-tenofovir disoproxil fumarate is a generally well-tolerated option for maintaining viral suppression in patients considering a change in therapy.”

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