Real-world Implementation of Dolutegravir-Lamivudine to Achieve and Maintain HIV-1 Viral Suppression at an Academic Medical Center

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BACKGROUND

Two drug regimens for the treatment of HIV-1 infection have the potential to decrease toxicity, limit drug exposure, reduce cost, and decrease chance for drug interactions[1,2]

Dolutegravir-Lamivudine (DTG-3TC) combines a high resistance barrier integrase inhibitor (INSTI) with a nucleoside reverse transcriptase inhibitor (NTRI) and was approved for use in April 2019[1]

Two phase 3 trials (GEMINI-1 and 2) previously established safety and efficacy among antiretroviral (ARV) naïve adults

- Guideline recommendations limited to inclusion criteria HIV RNA <500,000copies/mL and without Hepatitis B coinfection[1,3]

A phase 3 switch (TANGO) study established maintenance of viral suppression after switch from previous ARV regimen

- Previously on three or four drug tenofovir alafenamide (TAF) regimens[4]

ENDPOINTS

Primary: Incidence of patients initiated on DTG-3TC to determine early uptake in real-world practice

Secondary:

- Patient demographics (gender, race/ethnicity, age, years since HIV-1 diagnosis, previous antiretroviral (ART) exposure, insurance coverage)
- Viral outcomes (baseline CD4 and viral load, CD4 and viral load after initiation of DTG-3TC, change in CD4 and viral load)

METHODS

Study Design: Retrospective, descriptive, non-interventional chart review (April 2019 through March 2020)

Inclusion Criteria	Exclusion Criteria
• Patients prescribed DTG-3TC from the combined outpatient practices at Temple University Health System	• Patients prescribed DTG-3TC as part of inpatient discharge with no corresponding outpatient HIV follow up with a Temple provider • Age < 18 years • Pregnant women • Prisoners

RESULTS

Table 1: Baseline characteristics

Outcome	n=49 (%)
Gender (male)	34 (69)
Race/ethnicity	
Black	22 (45)
Hispanic	13 (26.5)
White	14 (28.5)
Age (median [IQR])	55 [46-60]
Years since diagnosis (from 2020) (mean [SD])	2.55 [1.24]
Insurance State-funded	44 (90)
Treatment indication for DTG-3TC Switch from previous regimen	47 (96)
Median length of therapy through 4/1/2020	110 days
Previous ART exposure greater than 10 years	26 (62)^

^Available information in only 42 records

Figure 1: Percentage of previous regimens prior to DTG-3TC initiation

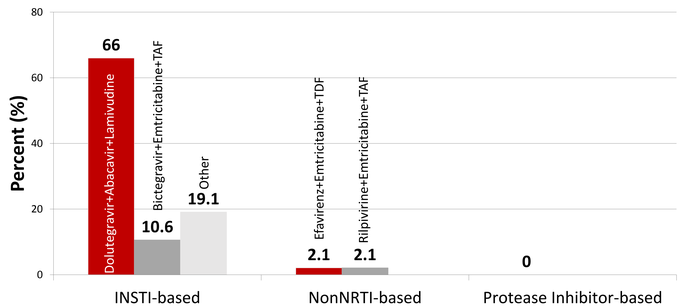


Table 2: Viral, renal, and weight outcomes after switching from previous therapy to DTG-3TC

Outcome	Baseline median [IQR]	Post-initiation median [IQR]	Difference (Δ) median [IQR]
CD4 count (cells/mm^3)	697 [516-942] (n=47)	735 [541-911] (n=20)	59 [44-106]
Viral load (copies/mL)	0 [0-0]^ (n=47)	0 [0-0]^ (n=21)	0 [0-0]^
Serum creatinine (mg/dL)	1.11 [0.99-1.49] (n=47)	1.11 [0.93-1.33] (n=23)	-0.06 [-0.15-0.06]
Weight (kg)	82 [73-94] (n=47)	81 [76-94] (n=23)	1 [-0.5-2.5]

^correlates to viral loads reported as either <20 or <40 copies/mL

Figure 2: Percentage of patients switching to DTG-3TC for medication modernization or adverse effects

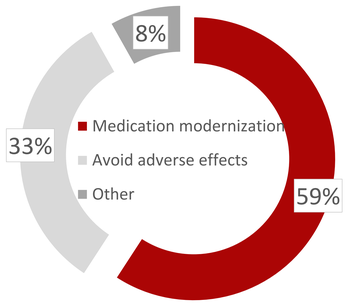
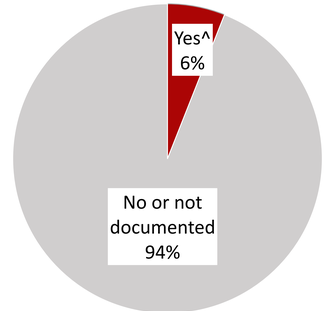


Figure 3: Percentage of patients experiencing side effects after initiation of DTG-3TC



^ self-limiting diarrhea, tingling in extremities, tiredness

CONCLUSION

- **Successful implementation of DTG-3TC has been seen in HIV practice among virally suppressed treatment switch patients**
- **Patients with longer exposure to ARV and time since diagnosis were frequently switched to DTG-3TC**
- **No immediate clinically relevant changes in CD4, viral load, serum creatinine, or weight were seen**

REFERENCES

1. US Department of Health and Human Services, Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. Available at https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.
2. Back, D. 2-Drug regimens in HIV treatment: pharmacological considerations. Germs 2017;7(3):113-114.
3. Cahn P, Sierra Madero J, Arribas J, et al. Dolutegravir plus lamivudine versus dolutegravir plus tenofovir disoproxil fumarate and emtricitabine in antiretroviral naïve adults with HIV-1 infection (GEMINI-1 and GEMINI-2): week 48 results from two multicenter, double blind, randomized, noninferiority, phase 3 trials. Lancet 2019;393(10167):143-155.
4. Van Wyk J, Ajana F, Bisshop F, et al. Efficacy and safety of switching to dolutegravir/lamivudine fixed dose two drug regimen versus continuing a tenofovir alafenamide based three or four drug regimen for maintenance of virologic suppression in adults with HIV-1: Phase 3 randomized, noninferiority TANGO study. Clin Infect Dis 2020 [epub ahead of print] doi: 10.1093/cid/ciz1243.

DISCLOSURES

DEK has participated in Advisory Boards for Thera and Janssen and has consulted for Abbvie and Gilead. The remaining authors have nothing to disclose.