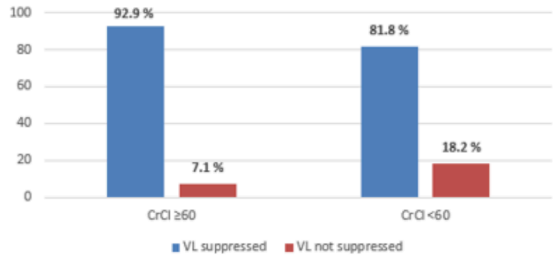
Table 1: Baseline demographics

Variables	Overall (n= 36)	CrCl ≥ 60 mL/min (n= 14)	CrCl < 60 mL/min (n= 22)
Age (years; median [range])	58.5 (25-84)	57.5 (25-70)	59.9 (44-84)
Gender			
Male	18 (50%)	5 (35.7%)	13 (59.1%)
Female	18 (50%)	9 (64.3%)	9 (40.9%)
Race			
Black or African-American	36 (100%)	14 (100%)	22 (100%)
Average length of HIV diagnosis (years)	13.7	13.7	13.7
History of AIDS			
Yes	17 (47.2%)	5 (35.7%)	12 (54.5%)
No	19 (52.8%)	9 (64.3%)	10 (45.5%)
HIV-1 RNA <50 copies/mL	33 (91.7%)	12 (85.7%)	21 (95.5%)
Mean CD4 counts (cells/mm^3)	670	722	637
Average duration of therapy with study drug (years)	1.95	1.95	1.95

Figure 2: Percent of patients with viral load (VL) suppression at 6 months



Conclusion. The use of dolutegravir and rilpivirine for the treatment of HIV infection in adults with CKD or ESRD on hemodialysis was both safe and effective in African American population.

Table 2: Reasons for discontinuation

Reasons for Discontinuation	CrCl ≥ 60 mL/min	CrCl < 60 mL/min	Details
Resistance	0	1	1. Uncontrolled viral load at 6 months 2. Study drug discontinued at 12 months
Headache	0	1	1. Uncontrolled viral load at 6 months from non-adherence from headache 2. Study drug discontinued at 8 months
Drug-Drug interaction (DDI)	0	1	1. Uncontrolled viral load at 36 months from DDI with sodium bicarbonate 2. Study drug discontinued at 36 months
Total	0	3	

Table 3: Subgroup analysis for patients with CrCl under 60 mL/min at baseline

Renal Impairment	Viral load Suppression at 6 months	Reason for Unsuppressed Viral load
Mild to moderate renal impairment (CrCl: 30 - 60 mL/min)	10/11 (90.9%)	1 patient: from resistance
Severe renal impairment (CrCl < 30 mL/min) on hemodialysis	4/5 (80.0%)	1 patient: unexplained high viral load reported at 6 months but became undetectable at 7 months
Severe renal impairment (CrCl < 30 mL/min) not on hemodialysis	4/6 (66.7%)	1 patient: from non-adherence due to headache 1 patient: from non-adherence

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900. Switching to DTG/3TC Fixed-Dose Combination (FDC) Is Non-inferior to Continuing a TAF-Based Regimen (TBR) in Maintaining Virologic Suppression Through 144 Weeks (TANGO Study)

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Background. DTG/3TC is a complete 2-drug regimen (2DR) for the treatment of HIV-1 infection. Non-inferior virologic efficacy has been proven over 3 years in treatment-naive people living with HIV (PLWH) and 2 years in a stable switch setting.

Methods. TANGO, a randomized, open-label, non-inferiority study, evaluates efficacy and safety of switching to DTG/3TC in PLWH who are virologically suppressed (> 6 months, no prior virologic failure [VF], no major NRTI/INSTI resistance) vs remaining on a 3- or 4-drug TAF-based regimen (TBR), stratified by baseline 3rd agent class. Week 144 analyses assessed non-inferiority (NI) with a 4% NI margin for Snapshot virologic failure (VF) and 8% for virologic success (VS; FDA Snapshot algorithm, intention-to-treat–exposed [ITT-E] population).

Results. Of 741 randomized/exposed pts (DTG/3TC: 369; TBR: 372), most pts entered the study on EVG/c (66%). For Week 144 Snapshot VF, switching to DTG/3TC was non-inferior to continuing TBR in the ITT-E analysis: 0.3% vs 1.3%; adjusted difference (95% CI): −1.1% (−2.4%, 0.2%) and superior to TBR in the per-protocol analysis: 0% vs 1.1%; adjusted difference: −1.1% (−2.3, −0.0); *P*=0.044 (2-sided). Snapshot VS was high in both arms and demonstrated non-inferiority (Table). Zero pts on DTG/3TC and 3 (0.8%) on TBR met confirmed virologic withdrawal criteria with no resistance observed. Zero pts on DTG/3TC and 6 (1.6%) on TBR discontinued for lack of efficacy. Overall AE rates were similar between arms (Table). TC, LDL-C, and triglycerides improved with DTG/3TC, HDL-C improved with TBR, with no difference in TC/HDL-C ratio between arms. Changes in eGFR (cystatin C) and proximal tubular function marker were similar across arms. Adjusted mean change from BL in weight was 2.2 and 1.7 kg in the DTG/3TC and TBR arms, respectively, and proportion of pts with > 10% weight increase was similar across arms (13% and 12%, respectively).

Table. Efficacy and Key Safety Results for the ITT-E and Safety Population

Week 144 study outcome by Snapshot analysis (ITT-E population), n (%)	**DTG/3TC (N=369)**	**TBR (N=372)**
HIV-1 RNA ≥50 c/mL (Snapshot virologic failure)	1 (0.3%)	5 (1.3%)
HIV-1 RNA <50 c/mL (Snapshot virologic success)[a]	317 (85.9%)	304 (81.7%)
No virologic data in Week 144 window	51 (13.8%)	63 (16.9%)
Week 144 virologic success for efficacy evaluable population,[b] n (%)	**(N=364)**	**(N=370)**
HIV-1 RNA <50 c/mL (Snapshot virologic success)	317 (87.1%)	304 (82.2%)
Key safety results (safety population), n (%)	**(N=369)**	**(N=371[c])**
Any AEs	336 (91%)	335 (90%)
AEs or deaths leading to withdrawal	23 (6%)	7 (2%)
Drug-related grade 2-5 AEs	21 (6%)	13 (4%)
Serious AEs[d]	57 (15%)	44 (12%)

[a]Snapshot virologic success adjusted difference in (DTG/3TC) − TBR: 4.2% (95% CI: −1.1%, 9.5%). Estimates and confidence intervals were based on a stratified analysis using Cochran-Mantel-Haenszel weights adjusting for baseline third agent class.
[b]Sensitivity analysis excluding 5 and 2 participants in the DTG/3TC and TBR arms who had missing data due to COVID-19 pandemic impact. Snapshot virologic success adjusted difference in (DTG/3TC) − TBR: 4.9% (95% CI: −0.3%, 10.2%).
[c]1 participant was excluded due to receiving a TDF-based regimen instead of a TAF-based regimen.
[d]3 deaths (1 homicide, 1 substance abuse, and 1 ischemic hepatitis), all unrelated to treatment, occurred in the DTG/3TC arm.

Conclusion. Switching to the 2-drug regimen of DTG/3TC from a TAF-based 3- or 4-drug regimen resulted in high, non-inferior efficacy with zero confirmed virologic withdrawals and good tolerability over 3 years of treatment. DTG/3TC 2DR is a robust switch option with durable efficacy, good safety and tolerability, and a high barrier to resistance.

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901. Integrated Community Health Screening for COVID-19 and HIV Promotes HIV Diagnoses and Linkage to Care

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