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REAL-WORLD TREATMENT EXPERIENCE OF SINGLE TABLET DOLUTEGRAVIR/LAMIVUDINE IN THE US: RESULTS FROM THE TANDEM STUDY

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Key Takeaways

- **TANDEM aimed to characterize real-world prescribing behaviors and treatment outcomes in the United States (US).**
- **Out of a total population of 469, 318 received dolutegravir/ lamivudine (DTG/3TC), of whom 126 were naïve to antiretroviral therapy (ART), and 192 were stable-switch (SS).**
- **After an average follow-up time of >1 year, 93.7% of treatment-naïve PLWH achieved virological suppression while receiving DTG/3TC and 95.8% of SS PLWH maintained virological suppression on DTG/3TC following switch.**
- **TANDEM reflects results from phase 3 clinical trials demonstrating DTG/3TC is an effective and well tolerated regimen with few treatment discontinuations.**
- **Primary reasons for initiation of DTG/3TC were to avoid long term toxicities (both cohorts), simplification/ streamlining of treatment (for SS sub-cohort) and convenience (for treatment-naïve sub-cohort).**

Introduction

- Treatment for People Living With HIV-1 (PLWH) continues to advance with a two-drug regimen (2DR) approach. [1]
- DTG/3TC is indicated as a 2DR for both treatment-naïve and virally suppressed PLWH. [2]
- Treatment with 2DRs has the potential to decrease lifetime cumulative drug exposure and long-term toxicities associated with multiple antiretrovirals. [3]
- DTG/3TC demonstrated non-inferiority vs. DTG+ tenofovir disoproxil fumarate/emtricitabine out to 3 years in the phase 3, double-blinded GEMINI-1 and GEMINI-2 trials.[4]
- Despite sustained virologic efficacy for DTG-based 2DRs observed in clinical trials, there is limited evidence in US-based real-world clinical settings. The TANDEM study aimed to characterize real-world prescribing behaviors and treatment outcomes in the US.

Methods

- TANDEM was a US-based, retrospective chart review. 24 sites abstracted data from medical charts of PLWH who were initiated on DTG/3TC or dolutegravir / rilpivirine (DTG/RPV) prior to Sept/30/2020, with a minimum clinical follow-up of six months.
  - Minimum follow-up could include time post-discontinuation of either regimen.
- Clinical characteristics, treatment history and post-initiation outcomes were abstracted.
- Analyses were descriptive and no formal hypotheses were tested.
- Missing data were not imputed. Descriptive analyses were performed in IBM® SPSS® Data Collection Survey Reporter v7.5 software.
- Time to event outcomes were calculated using Kaplan-Meier estimators conducted in StataCorp, 2015. Stata statistical software: Release 16 (College Station, TX, StataCorp LP).

Inclusion Criteria

- ≥18 years old;
- Have a diagnosis of HIV-1 infection;
- Have a history of ART therapy consisting of 2DR;
- One of the antiretroviral therapies must be either DTG/3TC or DTG/RPV as a single-tablet regimen (STR);
  - DTG/3TC cohort**:**
    - Must have been initiated after 1st May 2019
    - Upon initiation, PLWH must have been either naïve (N) to ART or virologically suppressed defined as having HIV-1 RNA <50 copies/mL, on a stable ART regimen for ≥3 months upon DTG-based 2DR initiation (SS).
  - Results for the DTG/RPV cohort will be reported separately
- At least 6 months of clinical follow-up after initiation of DTG-based 2DR.

Results

PLWH Characteristics

- From an overall sample of 469 PLWH, 151 received DTG/RPV and 318 received DTG/3TC, of whom 126 were treatment-naïve and 192 were SS. 48.4% of treatment-naïve PLWH received DTG/3TC as part of a test and treat paradigm.
- Demographics of the treatment-naïve and SS DTG/3TC cohort are described in **Table 1.**
  - The treatment-naïve cohort had a younger mean age compared to the SS cohort (37.4 vs 49.1 years).
- Common treatment considerations for the SS cohort were comorbidities (25.0%) and polypharmacy (12.5%), and for the treatment-naïve cohort were limited access to healthcare (12.7%) and comorbidities (9.5%) (**Table 2**).
  - At the data cut-off, median time on DTG/3TC was 1.3 years (treatment-naïve) [IQR 0.8,1.8] and 1.6 years (SS) [IQR 1.2, 1.8].
  - In the SS cohort, PLWH had received a median of 8.6 years prior ART and 66.1% received ≥2 prior regimens.
- From the HCP perspective, the most common reasons for initiating DTG/3TC were avoidance of long-term toxicities in both treatment-naïve (32.5%) and SS (27.1%) cohorts (**Figure 1**).
  - In the SS cohort, simplification/ streamlining (25.0%) and managing existing toxicities/ intolerance issues (12.5%) were also of high importance.
  - In the treatment-naïve cohort, convenience (15.9%), PLWH preference (12.7%) and weight gain (7.9%) were also common considerations.

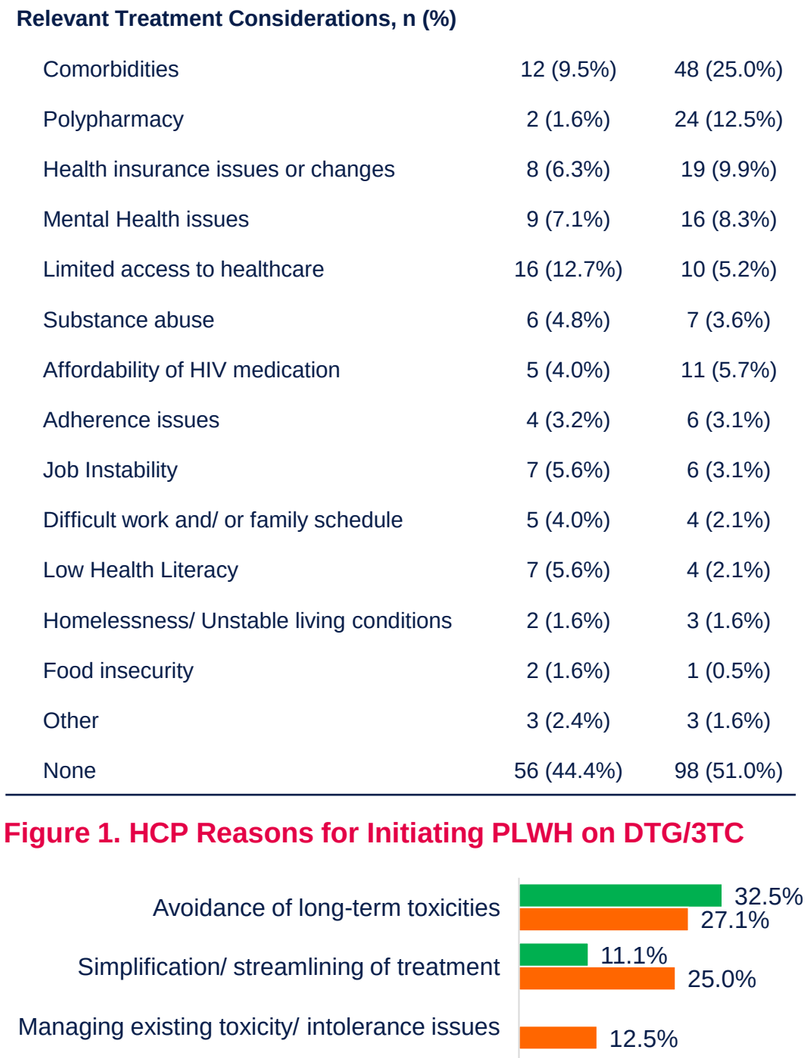
Table 1. DTG/3TC PLWH Demographics

	DTG/3TC Naïve (N) *n=126*	DTG/3TC Stable Switch (SS) *n=192*
Age (years)		
Mean (SD)	37.4 (±12.7)	49.1 (±12.4)
Assigned Sex at Birth, n (%)		
Male	111 (88.1%)	158 (82.3%)
Current gender identity, n (%)		
Cis-male	103 (81.7%)	148 (77.1%)
Cis-female	15 (11.9%)	34 (17.7%)
Trans-female	4 (3.2%)	2 (1.0%)
Race, n (%)		
White/ Caucasian	77 (61.1%)	124 (64.6%)
Black	36 (28.6%)	57 (29.7%)
Pacific islander	3 (2.4%)	0 (0.0%)
Asian	2 (1.6%)	2 (1.0%)
Not specified	5 (4.0%)	9 (4.7%)
Ethnicity, n (%)		
Hispanic / Latinx, n (%)	50 (39.7%)	48 (25.0%)
Current Insurance Coverage, n (%)		
Employee provided/ sponsored insurance	34 (27.0%)	64 (33.3%)
Privately arrange insurance	23 (18.3%)	41 (21.4%)
Medicare	8 (6.3%)	30 (15.6%)
Medicaid	22 (17.5%)	26 (13.5%)
Health insurance exchange plan	16 (12.7%)	14 (7.3%)
AIDS Drug Assistance Program (ADAP)	20 (15.9%)	14 (7.3%)
No insurance coverage	3 (2.4%)	3 (1.6%)

Table 2. DTG/3TC PLWH Characteristics

	DTG/3TC Naïve (N) *n=126*	DTG/3TC Stable Switch (SS) *n=192*
Median time on DTG/3TC, years (IQR)	1.3 (0.8,1.8)	1.6 (1.2,1.8)
Median prior ART duration, years (IQR)	-	8.6 (3.5,15.3)
Number of prior ART regimens, n (%)		
1	-	65 (33.9%)
≥2	-	127 (66.1%)
Relevant Treatment Considerations, n (%)		
Comorbidities	12 (9.5%)	48 (25.0%)
Polypharmacy	2 (1.6%)	24 (12.5%)
Health insurance issues or changes	8 (6.3%)	19 (9.9%)
Mental Health issues	9 (7.1%)	16 (8.3%)
Limited access to healthcare	16 (12.7%)	10 (5.2%)
Substance abuse	6 (4.8%)	7 (3.6%)
Affordability of HIV medication	5 (4.0%)	11 (5.7%)
Adherence issues	4 (3.2%)	6 (3.1%)
Job Instability	7 (5.6%)	6 (3.1%)
Difficult work and/ or family schedule	5 (4.0%)	4 (2.1%)
Low Health Literacy	7 (5.6%)	4 (2.1%)
Homelessness/ Unstable living conditions	2 (1.6%)	3 (1.6%)
Food insecurity	2 (1.6%)	1 (0.5%)
Other	3 (2.4%)	3 (1.6%)
None	56 (44.4%)	98 (51.0%)

Figure 1. HCP Reasons for Initiating PLWH on DTG/3TC



Note: Managing existing toxicity/ intolerance issues, food requirements, virological failure, low adherence without viremia and cost of ART were all n=0 (0%) within the DTG/3TC N cohort

Virological Outcomes

- 95.8% of SS PLWH maintained suppression while receiving DTG/3TC. Six of the 8 SS PLWH who then became detectable remained on DTG/3TC during the follow-up period, with 2 lost to follow-up **(Table 3)**.
- 93.7% of treatment-naïve PLWH achieved virological suppression and 83.3% remained suppressed.
- Five of the 6 treatment-naïve PLWH who rebounded remained on DTG/3TC, with 1 lost to follow-up. At point of abstraction, these 5 treatment-naïve PLWH had been on DTG/3TC for a median duration of 3.6 months post-rebound (IQR: 3.3 – 12.9 months) and 11.6 months total.
- N=1 treatment-naïve and N=3 SS PLWH discontinued DTG/3TC by the data cut-off.

Table 3. Virological Outcomes

	DTG/3TC Naïve (N) *n=126*	DTG/3TC Stable Switch (SS) *n=192*
Virological status of SS PLWH, n (%)		
Remained virologically supressed	**-**	**184 (95.8%)**
Became detectable, remained on DTG/3TC and resuppressed	-	4 (2.1%)
Became detectable, remained on DTG/3TC and not resuppressed	-	2 (1.0%)
Don't know	-	2 (1.0%)
Virological status of N PLWH, n (%)		
Became virologically supressed	**118 (93.7%)**	**-**
- Then rebounded	6 (4.8%)	-
- Then remained supressed	105 (83.3%)	-
- Then lost to follow-up	7 (5.6%)	-
Remained virologically detectable	3 (2.4%)	-
Don't know/ lost to follow-up	5 (4.0%)	-
Time from DTG/3TC initiation to PLWH becoming suppressed (weeks)		
Median (IQR)	10.4 (5.7,19.1)	-
Discontinuation, n (%)		
Discontinued DTG/3TC	1 (0.8%)	3 (1.6%)
Ongoing DTG/3TC	123 (97.6%)	188 (97.9%)
Unknown/ lost to follow-up	2 (1.6%)	1 (0.5%)
Time from initiation to discontinuation (weeks)*		
Median (IQR)	60.9 (60.9, 60.9)	29.6 (21.5, 74.3)
Reason for discontinuation, n (%)*		
Viremia (persistent low level/ viral blips)	1 (0.8%)	0 (0.0%)
Toxicity/ intolerance	0 (0.0%)	1 (0.5%)
Concerns about weight gain	0 (0.0%)	1 (0.5%)
PLWH preference	0 (0.0%)	1 (0.5%)

** Note: Discontinuation data is based on N=1 (0.8%) discontinuation within DTG/3TC treatment-naïve cohort and N=3 (1.6%) discontinuations within DTG/3TC SS cohort.*

Conclusions

- TANDEM provides real world evidence supporting DTG/3TC use in the US.
- Almost all PLWH who initiated DTG/3TC experienced sustained virological suppression, with few treatment discontinuations.
- Primary reasons for initiation of DTG/3TC were to avoid long term toxicities (both cohorts), simplification/ streamlining of treatment (for SS sub-cohort) and convenience (for treatment-naïve sub-cohort).
- TANDEM reflects results from phase 3 clinical trials demonstrating DTG/3TC is an effective and well tolerated regimen when used in real-world settings in both treatment-naïve and SS PLWH.

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