

Figure 1. Comparison of HIV-1 DNA and HIV-1 RNA between AHI and CHI. (a) Comparison of HIV-1 DNA between AHI and CHI, $p < 0.05$. (b) Comparison of HIV-1 RNA between AHI and CHI, $p > 0.05$.

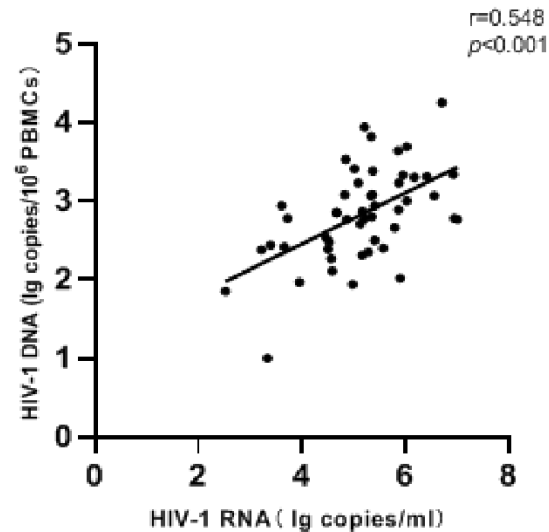


Figure 2. Correlation between HIV-1 RNA and HIV-1 DNA in AHI Group

Conclusion. Patients with AHI have lower HIV-1 DNA levels and smaller viral reservoir than those with CHI. These data have illustrates the benefits of rapid treatment. The correlation between HIV-1 DNA and HIV-1 RNA in patients with acute infection is strong, the level of HIV-1 DNA increased with the increase of HIV-1 RNA level, but was not related to CD4 + T cells, CD8 + T cells and CD4/CD8 ratio.

Disclosures. All Authors: No reported disclosures

898. Effectiveness and Tolerability of DTG + 3TC in Clinical Practice: Evidence in PLHIV from Real-world Data

Lee A. Evitt, MSc Health Economics¹; Rahul Kumar, M Pharmacy²; Rahul Kamath, PharmD³; Diwakar Jha, Masters in Pharmaceutical Sciences⁴; Daniel Parks, PhD⁵; Jean A. van Wyk, MB,ChB¹; Annemiek de Ruiter, MBBS FRCP⁶; ¹ViiV Healthcare, London, UK; ²GlaxoSmithKline Knowledge Centre, Gurgaon, Haryana, India; ³GlaxoSmithKline Knowledge Centre, Gurugram, Haryana, India; ⁴GlaxoSmithKline Knowledge Center, Gurgaon, Haryana, India; ⁵GlaxoSmithKline, Collegeville, PA; ⁶ViiV Healthcare, London, UK

Session: P-51. HIV: Treatment

Background. Randomized controlled trials have shown dolutegravir (DTG) + lamivudine (3TC) to be an efficacious, well-tolerated and durable regimen for treatment-naïve and treatment-experienced people living with HIV (PLHIV). Several observational studies have also concluded that it is effective in clinical practice. The objective of this meta-analysis was to estimate effectiveness and tolerability of DTG + 3TC in PLHIV by combining real-world evidence from clinical practice.

Methods. A systematic literature review using PubMed and Embase plus 24 regional and international conferences was conducted between January 2013 and December 2020 to identify studies of DTG + 3TC in treatment-experienced and treatment-naïve PLHIV in clinical practice. Eligible published articles reporting virologic suppression, virologic failure and discontinuations at Weeks 48 and 96 were identified and extracted. Identified studies were included if they had an acceptable level of publication bias and heterogeneity determined using funnel plots and I^2 statistics, respectively. One-arm meta-analyses using the DerSimonian and Laird method were conducted to estimate effect sizes for outcomes of interest for DTG + 3TC.

Results. One study of DTG + 3TC was identified reporting outcomes of interest at time points of interest in treatment-naïve PLHIV, hence no meta-analysis was undertaken in this population. Eight studies (N=2366 PLHIV) undertaken in Europe

reported data on treatment-experienced, virologically suppressed PLHIV on outcomes of interest at time points of interest (not all endpoints/time points were reported by all studies). The meta-analysis of available data from these 8 studies showed that among PLHIV switching to DTG + 3TC treatment, $\geq 95\%$ maintained virologic suppression (per protocol) with $\sim 1\%$ virologic failures on DTG + 3TC at Weeks 48 and 96. Five of the 8 studies reported resistance data. Among participants with baseline resistance testing, no treatment-emergent integrase strand transfer inhibitor resistance mutations were observed.

Table. Meta-analysis Results in Treatment-Experienced PLHIV: Proportion with Virologic Failure, Virologic Suppression, and Discontinuations at Weeks 48 and 96

	DTG + 3TC			
	Virologic failure*	Virologic suppression** Snapshot-type analysis	Per protocol	All-cause discontinuations***
Week 48, mean [95% CI]; (n/N)	0.011 [0.004-0.021] (26/2092)	0.853 [0.827-0.877] (694/819)	0.988 [0.976-0.996] (2031/2058)	0.131 [0.108-0.156] (111/819)
Week 96, mean [95% CI]; (n/N)	0.010 [0.002-0.022] (32/1823)	0.879 [0.766-0.960] (703/857)	0.984 [0.964-0.997] (2052/2106)	0.116 [0.045-0.211] (140/857)

*Virologic failure = HIV-1 RNA >40 c/mL in 2 consecutive determinations or ≥ 50 c/mL in 2 consecutive determinations or a single HIV-1 RNA determination ≥ 1000 c/mL (study definition dependent). Calculated using ITT population.

**Virologic suppression = HIV-1 RNA <50 c/mL. Calculated using both PP and ITT (Snapshot).

***All-cause discontinuations. Calculated using ITT.
n = number of events; N = total number of PLHIV evaluated for the event.

Conclusion. DTG + 3TC is an effective, tolerable and durable antiretroviral regimen with low rates of discontinuation in treatment-experienced PLHIV in clinical practice.

Disclosures. Lee A. Evitt, MSc Health Economics, ViiV Healthcare (Employee, Shareholder of GSK) Rahul Kumar, M Pharmacy, GlaxoSmithKline (Employee) Rahul Kamath, PharmD, GlaxoSmithKline (Employee) Diwakar Jha, Masters in Pharmaceutical Sciences, GlaxoSmithKline (Employee) Daniel Parks, PhD, GlaxoSmithKline (Employee, Shareholder) Jean A. van Wyk, MB,ChB, GlaxoSmithKline (Shareholder) ViiV Healthcare (Employee) Annemiek de Ruiter, MBBS FRCP, GlaxoSmithKline (Shareholder) ViiV Healthcare (Employee)

899. Use of Dolutegravir/Rilpivirine in Treatment of HIV in PLWH with CKD and ESRD

Jungwook Kang, Pharm.D.¹; Yae Ji Kim, Pharm.D. BCACP, AAHPV²; ¹Memorial Sloan Kettering Cancer Center, New York, NY; ²Touro College of Pharmacy, New York, NY

Session: P-51. HIV: Treatment

Background. Dolutegravir and rilpivirine is a novel two-drug single-tablet regimen for human immunodeficiency virus (HIV) that does not require dose adjustment in patients with chronic kidney disease (CKD) or end-stage renal disease (ESRD). Although there are no studies proving the efficacy and safety of this regimen for patients with CKD and ESRD, there are a few studies that support the use of dolutegravir in hemodialysis.

Methods. A retrospective chart review was performed on patients who received dolutegravir and rilpivirine from November 2017 to July 2020 in the HIV clinic at SUNY Downstate Medical Center. The primary endpoint was the viral load suppression rate (defined as viral load less than 50 copies/ml) at 6 months of therapy compared between two groups of patients with varying kidney function: chronic kidney disease (defined as creatinine clearance (CrCl) under 60 mL/min) and normal kidney function (defined as CrCl higher than or equal to 60 mL/min). Viral load suppression rate was compared using logistic regression. Secondary outcomes were any reported adverse drug events and the discontinuations of the study medication.

Results. Overall viral load suppression at 6 months was achieved in 31 out of 36 patients (86.1%). 13 out of 14 patients (92.9%) with CrCl greater than or equal to 60 mL/min at baseline achieved viral load suppression at 6 months, whereas 18 out of 22 patients (81.8%) with CrCl under 60 mL/min at baseline achieved viral load suppression at 6 months ($p=0.367$). With adjustments for age, gender, and the history of Acquired Immunodeficiency Syndrome, the result was still insignificant. One adverse event of headache was reported in the group with baseline CrCl under 60 mL/min. Three cases of discontinuation were reported in this group due to resistance, headache, and drug-drug interaction.

Figure 1: Patient selection

