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Session: P-47. HIV: Treatment

Background. Recently, an association between CYP2B6 516 G > T polymorphism and weight change was observed among African people living with HIV (PLWH) who were started on efavirenz(EFV)-based antiretroviral therapy (ART). We aimed to investigate the effect of EFV mid-dose plasma concentration on weight change among Taiwanese PLWH.

Methods. The medical records of adult PLWH who were taking EFV-containing ART and had been enrolled in a EFV therapeutic drug monitoring study between Oct 2009 and May 2014 were accessed. EFV mid-dose plasma concentration (C12) was determined in the previous study and those with serial weight measurements within 48 weeks around the time of EFV C12 measurement were included in the present study. The weight change in the 48 weeks and its associations with mid-dose EFV concentrations and CYP2B6 516 G > T polymorphism were examined by general estimating equations (GEE) after adjusting for age, baseline HIV viremia, baseline weight, and the companion backbone antiretroviral agents.

Results. One-hundred and fifteen predominantly male (94.8%) PLWH were included in this study (Table 1). The mean CD4 lymphocyte count was 542 cells/ μ L at the beginning of the observation and 94.8% achieved HIV viral suppression. Forty-four (38.3%) patients had non-wildtype CYP2B6 516 G > T polymorphism. On average, the included PLWH gained 0.8 kilogram at 48 weeks and the weight change did not differ among those with wildtype and non-wildtype CYP2B6 516 G > T (Figure 1). In the GEE models, CYP2B6 516 G > T polymorphism was not associated with weight change ($p=0.81$), instead, higher EFV C12 was found to be independently associated with less weight gain ($p=0.045$).

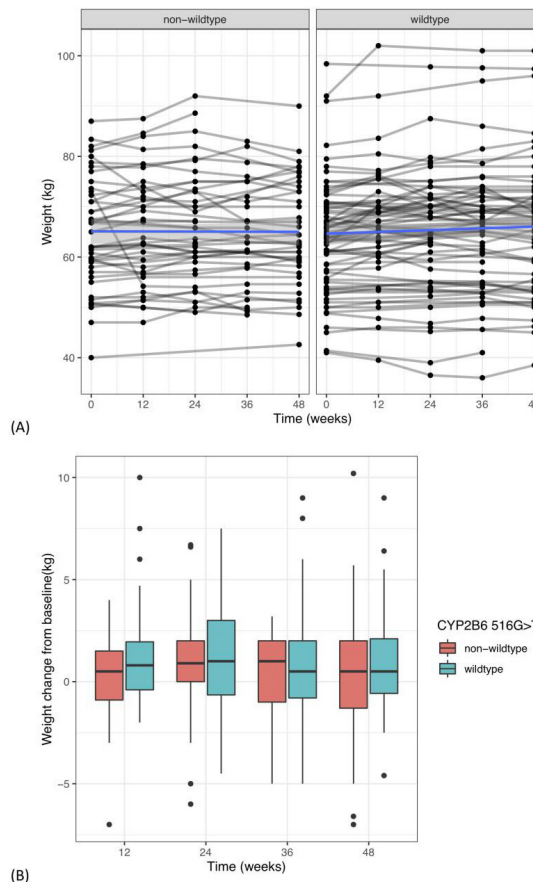
Table 1. Baseline characteristics.

	CYP2B6 516G>T Non-wildtype N=44	CYP2B6 516G>T Wildtype N=71	p-value
Age, year, mean (SD)	39.8 (10.3)	40.2 (9.7)	0.828
Male, n(%)	42 (95.5)	67 (94.4)	>0.999
Height, cm, mean (SD)	170.8 (6.0)	170.1 (6.4)	0.575
NRTI backbone, n(%)			0.538
AZT/3TC	13 (29.5)	26 (36.6)	
ABC/3TC	13 (29.5)	23 (32.4)	
TDF/XTC	18 (40.9)	22 (31.0)	
Nadir CD4 lymphocyte count, cells/ μ L, mean (SD)	323 (207)	255 (217)	0.101
CD4 lymphocyte count at the beginning of the study, cells/ μ L, mean (SD)	601 (328)	510 (345)	0.293
Plasma HIV RNA load>200 copies/ml at the beginning of the study, n(%)	4 (9.1)	2 (2.8)	0.299
Duration on EFV, months, mean (SD)	58.3 (51.2)	66.4 (54.5)	0.430
Weight at the beginning of the study, kg, mean (SD)	64.4 (10.9)	64.2 (11.1)	0.911
Mid-dose EFV concentration, mg/L, mean (SD)	3.9 (1.6)	3.0 (1.0)	0.002

*3TC, lamivudine; ABC, abacavir; AZT, zidovudine; EFV, efavirenz; NRTI, non-nucleos(t)ide reverse transcriptase inhibitor; SD, standard deviation; TDF, tenofovir disoproxil fumarate; XTC, lamivudine or emtricitabine.

Figure 1. The absolute weight (A) and weight change from baseline (B) among patients with wildtype and non-wildtype CYP2B6 516G>T polymorphism.

Figure 1. The absolute weight (A) and weight change from baseline (B) among patients with wildtype and non-wildtype CYP2B6 516G>T polymorphism.



Conclusion. Our findings support that increased EFV exposure may have a negative effect on weight gain.

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1021. HIV-1 RNA Blips and Low-Level Replication During Phase III/IIIb Cabotegravir + Rilpivirine Long-Acting Studies Are Similar to Oral 3-Drug Therapy and Not Associated with Week 48 Virologic Outcome

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Session: P-47. HIV: Treatment

Background. Phase III/IIIb studies demonstrated cabotegravir (CAB) + rilpivirine (RPV) long-acting (LA) dosed every 4 weeks (Q4W) was noninferior to current antiretroviral regimen (CAR) (FLAIR and ATLAS) and CAB + RPV LA dosed every 8 weeks (Q8W) was noninferior to Q4W (ATLAS-2M) through Week 48 (W48). HIV-1 ribonucleic acid (RNA) blips (viral load [VL] ≥ 50 to < 200 c/mL) are common during antiretroviral therapy (ART) and generally not associated with subsequent virologic failure (2 consecutive HIV-1 RNA ≥ 200 c/mL). We compared the frequency of HIV-1 RNA blips and low-level qualitative and quantitative HIV-1 RNA replication among participants treated with CAB+RPV LA and oral CAR and assessed impact on virologic outcome.

Methods. Plasma samples collected at study visits were analyzed for HIV-1 RNA viral load using the Abbott RealTime HIV-1 assay and qualitative target detected (TD) or target not detected (TND) outcomes were provided for HIV-1 RNA < 40 c/mL. The HIV-1 SuperLow assay (bioMONTR Labs) was used to measure HIV-1 RNA < 2 c/mL at Baseline and W48.

Results. The proportion of participants with HIV-1 RNA blips was similar overall between Q4W CAB + RPV LA and CAR arms in FLAIR (38/283 [13%] vs 39/283 [14%]) and ATLAS (17/308 [6%] vs 23/308 [7%]). Presence of HIV-1 RNA blips in either arm was not associated with virologic non-response at W48 (HIV-1 RNA ≥ 50 c/mL per US Food and Drug Administration Snapshot). In ATLAS-2M, HIV-1 RNA blips were observed in 32/523 (6%; Q4W) and 18/522 (3%; Q8W) of participants, with W48 virologic nonresponse in 2 Q4W and 0 Q8W participants. TD outcomes at individual study visits were comparable between study arms for the 3 studies. At W48, the proportion of participants with HIV-1 RNA < 2 c/mL was similar to Baseline and similar between treatment groups in all studies.

Conclusion. The proportions of study participants with HIV-1 RNA blips, TD viral load results, and HIV-1 < 2 c/mL were similar between the Q4W and Q8W CAB+RPV LA and the oral 3-drug CAR arms through W48 in phase III/IIIb studies. HIV-1 RNA blips did not predict virologic nonresponse (Snapshot analysis) at W48.

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1022. Impact of Hospitalization on Antiretroviral Therapy for People Living with HIV

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Background. Persons living with HIV (PLWH) are frequently hospitalized for reasons often unrelated to HIV. Transitioning of antiretroviral therapy (ART) while inpatient may not always be an immediate priority due to lack of knowledge, formulary restrictions, and patient status. This could lead to medication errors and gaps in therapy, which can persist at discharge, and could lead to viral rebound and disease progression. The purpose of this study was to identify effects of hospitalization on ART for PLWH.

Methods. This was an IRB approved, multi-center, retrospective cohort study of patients with HIV and/or AIDS based on ICD codes. Patients were included if they were at least 18 years old, receiving outpatient ART prior to admission, and hospitalized between March 2016 and March 2018. Patients were excluded if they were pregnant and only received intravenous zidovudine during their hospitalization. The primary objective was to determine the rate of ART restarted during hospitalization. Secondary objectives included rate at which inpatient ART was modified compared to outpatient regimen, and risk factors associated with regimen modification.

Results. Of 400 patients screened, 295 (74%) patients were on an outpatient ART regimen and were included in the study. Approximately half, 51%, were on a single tablet regimen (STR) outpatient. This population was majority male (59%) and of black race (87%). Median age was 49 years. Median CD4 count was 160 cells/mm³, while median HIV RNA for those with detectable viral load was 57,095 copies/mL.

236 of 295 patients (80%) received ART during their inpatient stay. However, 70 (30%) of these patients received a regimen that differed from their outpatient ART regimen. 69% of regimens were modified for reasons other than to optimize therapy. Patient sex, place of admission, and receipt of a STR or multi-tablet regimen (MTR) as an outpatient did not significantly impact rate of regimen modification.

Conclusion. Ensuring appropriate transition of ART during hospitalization remains an area in need of improvement. No one specific factor was associated with whether outpatient ART was appropriately and accurately restarted during

hospitalization. Thus, there are many opportunities to improve transitions of care and antiretroviral stewardship.

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1023. Impact of Physical Therapy in the Management of Musculoskeletal Pain in HIV Patients

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Background. Musculoskeletal (MSK) pain is common in HIV patients in the ambulatory setting. Healthcare providers tend to prescribe opioids to control MSK pain in HIV patients, which increases the risk of opioid misuse. An interdisciplinary approach that includes physical therapy has been successful in managing MSK pain in various healthcare settings. Therefore, we sought to find the impact of recruiting a physical therapist (PT), on the number of opioid prescriptions and physical therapy referrals made by resident physicians to manage MSK pain in HIV patients.

Methods. We performed a retrospective chart review of all patients seen by Internal Medicine (IM) residents in an HIV clinic in Detroit, before (01/17-05/17; 2017 dataset) and after (01/18-05/18; 2018 dataset) recruiting a physical therapist to the healthcare team. We collected demographic and clinical data from both datasets. We also surveyed the residents to assess how the PT addition influenced their comfort and knowledge in treating MSK pain in HIV patients. IRB waiver was obtained.

Results. Results showed that of all HIV patients seen at the clinic, 28/249 (11%) and 37/178 (21%) had chronic MSK pain in the 2017 and 2018 datasets, respectively. In 2017, all 28 patients with MSK pain were prescribed opioids. This number significantly decreased in 2018 after the PT addition (10/37 patients; $p < 0.0001$). Moreover, the number of physical therapy referrals made by residents significantly increased after the PT addition (2017: 5/28 patients; 2018: 17/37 patients; $p = 0.03$). Residents also recommended non-opioid interventions including orthopedics referrals (7/37 patients), braces/orthotics (3/37 patients) and non-opioid analgesics (26/37 patients) to patients after the PT addition. Survey responses showed that 7/9 residents (78%) felt that the physical therapist was helpful in improving their examination skills or developing a treatment plan for patients.

The effect of recruiting a physical therapist on the number of opioid prescriptions and physical therapy referrals made by resident physicians

Intervention	Before PT recruitment (2017)	After PT recruitment (2018)	p-value ($\alpha = 0.05$)
Opioid prescriptions (%)	100%	27%	$p < 0.0001$
PT referrals (%)	18%	46%	$p = 0.03$

Conclusion. In conclusion, our results show that the addition of a physical therapist to the team encourages physicians to utilize non-opioid management of MSK pain in HIV patients. We also find that physicians are satisfied with taking an interdisciplinary approach to pain management in HIV patients.

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1024. Impact of Treatment Adherence on Efficacy of DTG/3TC and DTG + TDF/FTC: Pooled Analysis of the GEMINI 1 and 2 Clinical Trials

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Background. GEMINI 1 & 2 are global double-blind, multi-center phase III non-inferiority studies evaluating efficacy and safety of dolutegravir (DTG) + lamivudine (3TC) once daily in treatment-naive HIV-1-infected adults with Screening HIV-1 RNA $\leq 500,000$ c/mL (ClinicalTrials.gov: NCT02831673/NCT02831764). Participants were randomized 1:1 to treatment with DTG+3TC or DTG + tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC). The primary endpoint was the proportion of participants with plasma HIV-1 RNA < 50 c/mL at Week 48 (Snapshot algorithm). DTG+3TC was non-inferior to DTG+TDF/FTC at Weeks 48 and 96. Here we evaluate the impact of treatment adherence on Week 48 virologic response (VR) within the GEMINI trials as a post-hoc analysis.

Methods. Adherence was estimated using pill counts data and categorized as follows: $\geq 90\%$ vs $< 90\%$. Week 48 VR was measured as % of participants with HIV-1 RNA < 50 c/mL by Food and Drug Administration Snapshot and by last on treatment viral load (VL) for the intention to treat-exposed population for which adherence could be derived. VR and differences between treatment arms within each adherence category were calculated along with exact unadjusted 95% confidence intervals.