

Table 2 Univariable and Multivariable Factors associated with Renal Function Improvement (CrCl ≥ 60 ml/min) at 12 months after ABC Initiation

Factors	Univariate analysis			Multivariate analysis		
	Odds ratio	95% CI	P-value	Odds ratio	95% CI	P-value
Age <60 years	6.9	(1.92, 27.74)	0.003	4.26	(0.45, 39.62)	0.202
Male	1.2	(0.5, 2.8)	0.734	0.39	(0.07, 2.08)	0.271
BMI ≥ 23 kg/m ²	2.2	(0.9, 5.2)	0.073	1.13	(0.19, 6.64)	0.89
Previous AIDS-defining illness						
Pneumocystis pneumonia	1.9	(0.6, 5.8)	0.283			
Tuberculosis	0.8	(0.3, 2.5)	0.716			
Talaromycosis	1.5	(0.4, 5.6)	0.533			
Cryptococcus	2.7	(0.5, 14.2)	0.240			
Herpes infections	2.64	(0.35, 19.67)	0.343			
Co-morbidities						
Hypertension	0.4	(0.2, 1)	0.044	0.69	(0.15, 3.12)	0.631
Diabetes mellitus	0.3	(0.1, 1)	0.049	0.16	(0.02, 1.21)	0.077
Dyslipidemia	0.6	(0.3, 1.4)	0.244			
Hepatitis B infection	0.6	(0.3, 1.4)	0.244			
Duration of TDF exposure <6 years	1.7	(0.68, 4.24)	0.255	1.03	(0.22, 4.68)	0.968
Duration of TDF usage after detected CrCl <60 ml/min for <6 months	7.42	(2.56, 21.55)	<0.001	9.26	(2.07, 41.37)	0.004
Exposure to nephrotoxic agents within 6 months before ABC initiation	0.3	(0, 2.9)	0.323	0.56	(0.03, 8.86)	0.686
Exposure to NRTIs before ABC initiation						
Lamivudine (3TC)	0.4	(0, 6.4)	0.507			
Emtricitabine (FTC)	0.7	(0.2, 2.5)	0.634			
Tenofovir (TDF)	1.4	(0.3, 5.3)	0.656			
Stavudine (d4T)	0.6	(0.2, 1.4)	0.203			
Zidovudine (AZT, ADV)	1.1	(0.5, 2.7)	0.757			
Didanosine (ddI)	0.8	(0.1, 8.4)	0.881			
Exposure to NNRTIs before ABC initiation						
Efavirenz (EFV)	2.8	(1.1, 7.3)	0.035	1.89	(0.28, 12.55)	0.507
Nevirapine (NVP)	0.7	(0.3, 1.7)	0.411			
Rilpivirine (RPV)	1.5	(0.5, 4.9)	0.511			
Exposure to PIs before ABC initiation				0.06	(0.01, 0.76)	0.03
Lopinavir/ritonavir (LPV/r)	0.1	(0, 0.9)	0.044			
Indinavir/ritonavir (IDV/r)	2.6	(0.2, 42.7)	0.507			
Baseline CrCl ≥ 50 ml/min before ABC initiation	11.5	(3.9, 33.9)	<0.001	4.48	(0.7, 28.56)	0.112

CI, Confident interval; BMI; Body mass index; HSV; Herpes infection; TDF; Tenofovir disoproxil fumarate; ABC; Abacavir; NNRTIs: Nucleoside reverse transcriptase inhibitors, NRTIs: Non-nucleoside reverse transcriptase inhibitors

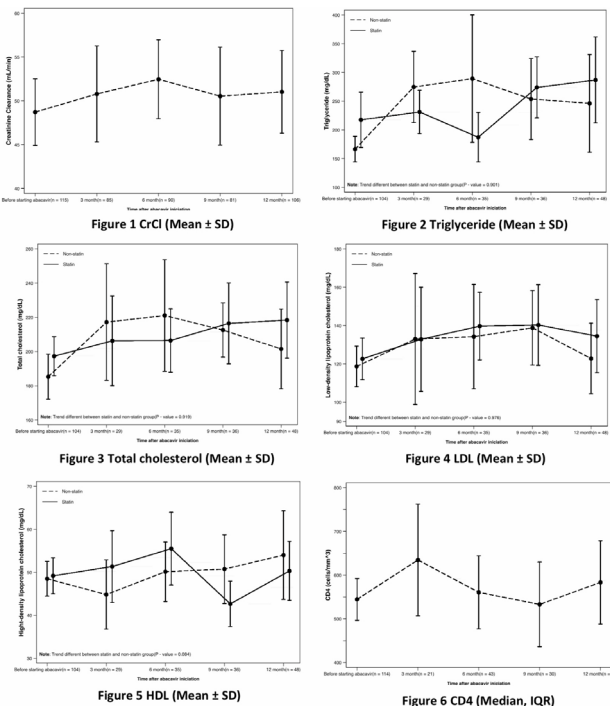


Figure. (1) Creatinine clearance (ml/min) during follow up period. (2) Triglyceride (mg/dl) during follow-up period. (3) Total cholesterol (mg/dl) during follow up period. (4) LDL (mg/dl) during follow up period. (5) HDL (mg/dl) during follow up period. (6) CD4 (cells/mm³) during follow up period

Conclusion. ABC used in Thai ART-experienced PLWH appeared to be effective with low CV event in the first year. Despite the statistically significant in the change of CrCl after ABC switching, the change was subtle and need further evaluation.

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877. North American Phase 3/3b Experience with Long-Acting Cabotegravir and Rilpivirine: Efficacy, Safety, and Virologic Outcomes

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Session: P-51. HIV: Treatment

Background. Cabotegravir (CAB) plus rilpivirine (RPV) is the first complete long-acting (LA) regimen recommended by treatment guidelines for the maintenance of HIV-1 virologic suppression. CAB+RPV LA dosed every 4 weeks (Q4W) or every 8 weeks (Q8W) demonstrated noninferior efficacy in multinational Phase 3/3b trials. This *post hoc* descriptive analysis summarizes efficacy, virologic outcomes, safety, and treatment preference for US and Canadian (CAN) participants through Week (W) 48.

Methods. This analysis focuses on data for US/CAN participants naive to CAB+RPV (n=376) from the larger pooled population of the ATLAS, FLAIR, and ATLAS-2M Phase 3/3b studies (N=1245). Endpoints included the proportion of participants with plasma HIV-1 RNA ≥ 50 and < 50 c/mL at W48 (FDA Snapshot algorithm), incidence of confirmed virologic failure (CVF; 2 consecutive HIV-1 RNA ≥ 200 c/mL), safety, and treatment preference through W48.

Results. 376 US/CAN participants received CAB+RPV LA Q4W or Q8W. Median (range) age was 39y (20–74); 14.9% were female, 66.0% were White. At W48, 93.1% (350/376) maintained virologic suppression (HIV-1 RNA < 50 c/mL), 1.9% (7/376) had HIV-1 RNA ≥ 50 c/mL, and 0.8% (3/376) met the CVF criterion, consistent with the overall global pooled population (Table 1). Two of the three participants with CVF had ≥ 2 of the three baseline factors (archived RPV resistance-associated mutations [RAMs], HIV subtype A6/A1, body mass index [BMI] ≥ 30 kg/m²) previously associated with CVF. Among the US/CAN participants with a single baseline factor, none met CVF. Overall, archived RPV RAMs were observed in 3.2% (12/376), HIV subtype A6/A1 in 1.1% (4/376), and BMI ≥ 30 kg/m² in 26.3% of participants. Safety and injection site reaction findings were similar to the overall pooled population (Table 2). Most participants (120/134, 89.6%) preferred LA over oral dosing (7/134, 5.2%).

Table 1. Snapshot outcomes following CAB+RPV LA Q4W and Q8W at Week 48 in participants naive to CAB+RPV from ATLAS, FLAIR, and ATLAS-2M (ITT-E population)

	US/CAN Q4W + Q8W (n=376)	Overall pooled Q4W + Q8W (N=1245)
HIV-1 RNA < 50 c/mL, n (%)	350 (93.1)	1156 (92.9)
HIV-1 RNA ≥ 50 c/mL, n (%)	7 (1.9)	21 (1.7)
Data in window not below threshold	4 (1.1)	6 (0.5)
Discontinued for lack of efficacy*	3 (0.8)	13 (1.0)
Discontinued for other reason while not below threshold	0	2 (0.2)
No virologic data, n (%)	19 (5.1)	68 (5.5)
Discontinued study due to AE or death	9 (2.4)	36 (2.9)
Discontinued study for other reason	10 (2.7)	32 (2.6)
On study but missing data in window	0	0

AE, adverse event; CAB, cabotegravir; CVF, confirmed virologic failure; ITT-E, intention-to-treat exposed; LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; RPV, rilpivirine; US/CAN, United States and Canada.

* Participants meeting the CVF criterion.

Table 2. Safety summary through Week 48 following CAB+RPV LA Q4W and Q8W or comparator ART in participants naive to CAB+RPV from ATLAS, FLAIR, and ATLAS-2M

Parameter, n (%)	US/CAN Q4W + Q8W (n=376)	US/CAN CAR (n=165)	Overall pooled Q4W + Q8W (n=1245)	Overall pooled CAR (n=591)
Any AE	351 (93)	114 (69)	1172 (94)	444 (75)
Excluding ISRs	307 (82)	114 (69)	1035 (83)	444 (75)
Any Grade ≥ 3 AE	37 (10)	13 (8)	119 (10)	35 (6)
Excluding ISRs	19 (5)	13 (8)	78 (6)	35 (6)
Any drug-related AE	301 (80)	5 (3)	1035 (83)	35 (6)
Excluding ISRs	82 (22)	5 (3)	335 (27)	35 (6)
Any Grade ≥ 3 drug-related AE	22 (6)	1 (<1)	58 (5)	1 (<1)
Excluding ISRs	2 (<1)	1 (<1)	14 (1)	1 (<1)
AE leading to withdrawal	9 (2)	4 (2)	42 (3)	9 (2)
Any SAE	9 (2)	10 (6)	51 (4)	25 (4)
Drug related	0	1 (<1)	3 (<1)	1 (<1)
Any fatal SAE	0	1 (<1)	0	1 (<1)
Drug related	0	0	0	0

AE, adverse event; ART, antiretroviral therapy; CAB, cabotegravir; CAR, current antiretroviral therapy; ISR, injection site reaction; LA, long-acting; Q4W, every 4 weeks; Q8W, every 8 weeks; RPV, rilpivirine; SAE, serious adverse event; US/CAN, United States and Canada.

Conclusion. In US/CAN Phase 3/3b trial participants, CAB+RPV LA was highly effective and well tolerated, with outcomes consistent with the overall pooled population. Baseline prevalence of archived RPV RAMs and subtype A6/A1 was low and aligned with regional prevalence/surveillance data. CAB+RPV LA provides a tolerable and effective injectable LA treatment option for virologically suppressed US/CAN individuals with HIV.

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878. Telemedicine Implementation in a Midwestern HIV Clinic: One Year Outcomes

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Session: P-51. HIV: Treatment

Background. During the COVID-19 pandemic, we realized the importance of limiting in-clinic interactions with patients who were stable on antiretroviral therapy to promote social distancing. Our HIV clinic adopted telemedicine practices, in line with the HHS Interim Guidance for COVID-19 and Persons With HIV. Several HIV clinics reported lower viral suppression rates during the pandemic. We aim to describe the implementation process as well as year one outcomes of telemedicine at our clinic.

Methods. In March 2020, we created telemedicine protocols; we also designed and continuously updated algorithms for determining patient eligibility for telemedicine based on recent viral loads and last clinic visit. We monitored outcomes through electronic medical record chart reviews between May 1, 2020, and April 30, 2021. We collected patient demographics, and federal poverty level (FPL) information. We collected baseline and post-intervention rates of viral load suppression (VLS, defined as HIV RNA < 200 copies per mL), medical visit frequency (MVF, defined as percentage of patients who had one visit in each 6 months of the preceding 24 months with at least 60 days between visits) and lost to care (LOC, no follow up within 12 months period).

Results. We conducted a total of 2298 ambulatory medical visits; 1642 were in person and 656 (29%) were telemedicine visits. Out of those, 2177 were follow up visits (649, 30% telemedicine). There was no difference of telemedicine utilization based on race (28% in African Americans vs. 32% in Whites); ethnicity (30% in Hispanic vs. 30% in Non-Hispanic); gender (24% in females vs. 30% in males); or FPL (28% in FPL < 200% vs. 31% in FPL >200%). By the end of April 2021, overall clinic VLS rate was 94%, MVF was 48%, and there were 40 patients LOC compared to 92%, 49%, and 43 patients in April 2020, respectively.

Conclusion. Telemedicine was a safe alternative to routine in-person HIV care during the COVID-19 pandemic. We observed similar rates of utilization across demographic and FPL status. Applying selection criteria, viral suppression and retention in care rates were not adversely impacted by shift to telemedicine modality.

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879. Evaluation of the Incidence of Hypertension, Diabetes, and Hyperlipidemia in Patients on Antiretroviral Therapy

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Session: P-51. HIV: Treatment

Background. Although integrase inhibitor (INSTI)-based regimens have been associated with weight gain, there is limited data on whether INSTIs cause long-term metabolic consequences. This study evaluated the effect of INSTIs on the development of metabolic comorbidities compared to non-nucleoside reverse transcriptase inhibitor (NNRTI) or protease inhibitor (PI)-based therapies in patients in the Illinois Department of Corrections.

Methods. This retrospective cohort study consisted of incarcerated adult patients living with HIV and receiving a guideline-recommended regimen between 7/12/10 and 12/31/19. Patients with a pre-existing diagnosis of diabetes, hypertension, or hyperlipidemia, or lack of medical follow-up data were excluded. The primary outcome was to compare the incidence of a metabolic comorbidity between regimens. Secondary outcomes compared the incidence of weight gain, diabetes, hypertension, and hyperlipidemia as separate outcomes between drug classes. Demographics and pertinent labs were collected. Data was analyzed with ANOVA, chi-squared, and

paired t-tests. The primary outcome was adjusted for age, race, use of antipsychotic medications, and family history of metabolic comorbidities.

Results. A total of 206 patients were included in the analysis with mean follow-up time of 31.5 ± 19.4 months. Majority of patients were Black (69%) and male (91%). A total of 42 patients developed a metabolic comorbidity (Table 1). After adjustment for confounding factors, there was a significant difference in the development of comorbidities between the treatment groups (p=0.031) with INSTI use being more likely to develop a comorbidity than NNRTI (p=0.004). No difference was found between INSTI and PI use (p=0.518). Development of hypertension was significantly higher in the INSTI group than NNRTI group (p=0.014), while the development of diabetes and hyperlipidemia were not. Weight and BMI were significantly higher regardless of antiretroviral (Table 2). No differences were found in the primary outcome between agents within the same drug class or between 1st or 2nd generation INSTIs.

Table 1. Results of Primary and Secondary Outcomes

	INSTI ^a (n=111)	PI ^b (n=47)	NNRTI ^c (n=48)	p-value
Development of a comorbidity, n (cases per 100 patient years)	29 (5.37)	10 (1.85)	3 (0.56)	0.031
Development of diabetes, n (cases per 100 patient years)	1 (0.19)	0 (0)	0 (0)	0.652
Time to diabetes development, months ± SD	34.0 ± 0	N/A	N/A	-
Development of hypertension, n (cases per 100 patient years)	21 (3.89)	8 (1.48)	2 (0.37)	0.027
Average time to hypertension development, months ± SD	18.5 ± 3.1	19.6 ± 6.6	10.5 ± 4.7	-
Development of hyperlipidemia, n (cases per 100 patient years)	11 (2.04)	3 (0.55)	1 (0.19)	0.205
Average time to hyperlipidemia development, months ± SD	29.6 ± 7.3	29.12 ± 12.8	N/A	-

Acronyms: INSTI = integrase inhibitor, n = number, N/A = not applicable, NNRTI = non-nucleoside reverse transcriptase inhibitor, PI = protease inhibitor, SD = standard deviation

^a INSTIs included bicittegravir, elvitegravir, dolutegravir, and elvitegravir

^b PIs included darunavir and atazanavir

^c NNRTIs included efavirenz and rilpivirine

Table 2. Impact of HIV regimen on weight and BMI after 1 year

	Average weight pre-regimen (lbs) ± SD	Average weight post-regimen (lbs) ± SD	p-value
INSTI ^a (n=105)	183.8 ± 36.4	193.3 ± 37.4	< 0.0001
PI ^b (n=42)	176.5 ± 33.6	182.2 ± 30.2	0.0036
NNRTI ^c (n=40)	178.0 ± 38.4	187.5 ± 38.1	0.003
	BMI pre-regimen (kg/m ²) ± SD	BMI post-regimen (kg/m ²) ± SD	p-value
INSTI (n=98)	26.8 ± 4.7	28.2 ± 4.7	< 0.0001
PI (n=24)	26.9 ± 4.8	27.9 ± 4.5	0.0074
NNRTI (n=27)	26.7 ± 5.0	28.0 ± 5.0	0.015

Acronyms: BMI = body mass index, INSTI = integrase inhibitor, lbs = pounds, n = number, NNRTI = non-nucleoside reverse transcriptase inhibitor, PI = protease inhibitor, SD = standard deviation

^a INSTIs included bicittegravir, elvitegravir, dolutegravir, and elvitegravir

^b PIs included darunavir and atazanavir

^c NNRTIs included efavirenz and rilpivirine

Conclusion. All antiretrovirals were linked to weight gain but INSTIs were associated with increased incidence of hypertension.

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880. Interim Analysis of Real-World Community-Based HIV Rapid Start Antiretroviral with BFTAF Versus Conventional HIV Antiretroviral Therapy Start – The RoChAChA Study, A Pilot Study

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Session: P-51. HIV: Treatment

Background. Trillium Health (TH) is a Federally Qualified Health Center look-alike and Ryan White C grantee in Rochester, NY providing primary and specialty care, including HIV prevention and treatment. Rapid Start Antiretroviral therapy (RSA) has been shown to decrease time to viral suppression while increasing linkage to and retention in care. However, data on a fixed-dose combination of BFTAF with these benefits are limited.

We aim to show RSA with BFTAF time to viral suppression, adherence to medication, and retention in care is statistically significant in comparison to older treatment models. Additionally, we aim to demonstrate the feasibility and acceptability of RSA with BFTAF.

Methods. This is an interim analysis of participants who enrolled in the study and been in care at TH for at least 3 months as of May 2021. All participants complete a baseline assessment and start BFTAF. Follow up visits are conducted through 48 weeks. Primary and secondary endpoints are included in the attached table 2 Barriers to care and patient reported outcomes were evaluated through a standardized questionnaire at the final study visit. Study results were compared with non-RSA historical control data from patients who received standard of care universal ART initiation at TH.