875. Indirect Treatment Comparison of 48-Week Efficacy and Safety of Cabotegravir + Rilpivirine Long-Acting Every 2 Months to Bictegravir/ Emtricitabine/Tenofovir Alafenamide in Suppressed HIV-1 Infected Participants

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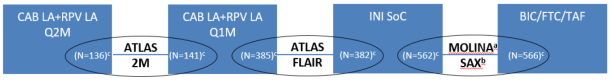
Background. Switching to cabotegravir long-acting + rilpivirine long-acting (CAB LA + RPV LA) administered every month (Q1M) has demonstrated non-inferiority in viral suppression versus a range of standard of care (SoC) antiretroviral regimens, including tenofovir alafenamide based regimens, in two pivotal phase 3 clinical trials (ATLAS [NCT02951052] and FLAIR [NCT02938520]). Furthermore, CAB LA + RPV LA every 2 months (Q2M) has demonstrated non-inferiority in maintaining viral suppression compared with CAB LA + RPV LA Q1M in a phase 3b study (ATLAS-2M [NCT03299049]). As bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) was not widely used at study initiation, the regimen was not present in the SoC arms of ATLAS and FLAIR. The objective was to compare efficacy and safety of CAB LA + RPV LA Q2M to BIC/FTC/TAF using indirect treatment comparison.

Methods. Two switch studies appropriate for facilitating indirect comparison to BIC/FTC/TAF were identified via systematic literature review (Molina et al. 2018 [NCT02603120] and Sax et al. 2020 [NCT03110380]). Indirect comparison using a generalisation of Bucher's methodology to calculate relative risk, odds ratio, and risk differences in efficacy (Week 48 HIV RNA < 50 c/mL and ≥50 c/mL per FDA Snapshot approach and CD4+ cell change from baseline) and safety (discontinuation due to adverse events [AEs] and overall and serious AEs excluding injection site reactions [ISRs]) was conducted. Results for CAB LA + RPV LA Q2M in ATLAS-2M participants with prior integrase inhibitor (INI) exposure, but without prior CAB exposure, were indirectly compared to those with prior INI use in ATLAS and FLAIR via the common CAB LA + RPV LA Q1M comparator and were then indirectly compared to BIC/FTC/TAF via the INI comparator (Figure 1).

Figure 1: Indirect treatment comparison of CAB LA + RPV LA Q2M versus BIC/FTC/TAF



[a]Molina et al. 2018 [NCT02603120]; [b]Sax et al. 2020 [NCT03110380]; [c]participants switching from integrase inhibitor (INI), but without prior CAB exposure.

Results. No statistically significant differences in virologic failure, virologic suppression, CD4+ cell change, discontinuations due to AEs, and non-ISR serious/non-serious AEs were found between CAB LA + RPV LA Q2M and BIC/FTC/TAF (Table 1).

Table 1: Efficacy and safety of CAB LA + RPV LA Q2M compared with BIC/FTC/TAF

	Comparative effect measure (95% CI) CAB LA + RPV LA Q2M vs BIC/FTC/TAF[b] at 48 weeks		
	Relative Risk	Odds Ratio	Risk difference, %
Virologic failure (HIV RNA ≥50 copies)	1.04 (0.09, 12.25)	1.04 (0.08, 12.70)	-0.01 (-3.84, 3.83)
Virologic suppression (HIV RNA <50 copies)	1.04 (0.95, 1.13)	1.52 (0.48, 4.77)	3.41 (-4.56, 11.37)
CD4+ cell change from baseline[a]			20.00 (-43.98, 83.99)
Discontinuation due to AEs	1.48 (0.23, 9.45)	1.48 (0.22, 9.93)	0.1 (-5.2, 5.4)
AEs (excluding ISRs)	1.06 (0.93, 1.21)	1.23 (0.54, 2.84)	4.54 (-6.34, 15.42)
Serious AEs (excluding ISRs)	4.13 (0.94, 18.06)	4.39 (0.94, 20.40)	5.84 (-0.77, 12.45)

[a] Mean difference, cells/µl; AE, adverse event; CI, confidence interval; ISR, injection site reaction

Conclusion. Indirect treatment comparison indicated efficacy and safety of CAB LA + RPV LA Q2M is not different from BIC/FTC/TAF. These regimens will be further compared in a randomized head-to-head non-inferiority trial (SOLAR, NCT04542070).

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876. Renal Function, Lipid Profile, and Cardiovascular Events After Switching to Abacavir Containing Regimen in Antiretroviral-Therapy-Experienced People Living with HIV in Northern Thailand

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Background. Abacavir (ABC) is commonly used as part of antiretroviral therapy (ART) regimen for people living with HIV (PLWH) with renal dysfunction in resource limiting countries. While the renal function changes and association with cardiovascular (CV) events have been well described in developed countries, these information is limited in Asian population. Herein, this study aims to describe the changes in renal function, lipid profile and CV events after ABC switching in ART-experienced PLWH in Northern Thailand.

Methods. This retrospective chart-review study was conducted among adults ART-experienced PLWH (≥18 years old) who received ABC-containing regimen during January 2016 to December 2018 at Maharaj Nakorn Chiang Mai Hospital. Demographic data, HIV-related treatments, creatinine, lipid profile and CV events were collected. Patients were categorized into early switching group and late switching group (CrCl≥50 ml/min and CrCl< 50 ml/min before switching to ABC). The change of CrCl, urinalysis profiles, lipid profiles, CD4, viral load, and cardiovascular events at 12 months after ABC initiation were assessed.

Results. Total of 115 participants were enrolled with mean age of 55.2±10.7 years and 63.5% were male. Of those, 87.8% of patients had received Tenofovir disoproxil fumarate (TDF) prior to ABC. Mean of CrCl at baseline was 47.6±16.8 ml/min and at 12th month was 49.56±19.42 ml/min with mean difference of 3.7 ml/min (95%CI 1.6-5.8, P< 0.001). The improvement of CrCl at 12 months in early switching group was statistically significant compared to late switching. Other two associated factors with improved CrCl after switching to ABC were duration of TDF exposure during CrCl< 60 ml/min (OR 9.26, P 0.004) and history of protease inhibitors (PIs) exposure (OR 0.06, P 0.03). No significant changed in lipid profile, CD4 and virological outcome overtime. There were only 2 CV events observed (9.3:1000 person-year, 95%CI 2.3-37.1).

Table 1 Baseline Characteristic of 115 Study Patients

Characteristics	N=115 (%)
Baseline demographic data (at the time of switching to ABC)	
Age (years, mean ± SD)	55.2 ± 10.7
Male	73 (64)
Weight (kg, mean ± SD)	59.8 ± 12.2
Height (cm, mean ± SD)	162.7 ± 8.4
Body mass index (kg/m^2, mean ± SD)	22.5 ± 3.7
Co-morbidities	
Hypertension	66 (57)
Diabetes mellitus	34 (30)
Dyslipidemia	64 (56)
Hepatitis B infection	7 (6)
Hepatitis C infection	4 (3)
Chronic kidney disease	54 (46.9)
HIV History	
Previous AIDS-defining illness	58 (50)
CD4 at the time of HIV diagnosis (cell/mm^3, median (IQR))	202.5 (112-411)
CD4 before switching to ABC (cell/mm^3, median (IQR))	501 (367-670)
History of drug resistant HIV, number	6 (5)
Kidney function (CrCl)	
Baseline CrCl at the time of HIV diagnosis (mL/min, mean ± SD)	62.8 ± 22.8
CrCl before switching to ABC (ml/min, mean ± SD)	47.6 ± 16.8
Switching reasons from others NRTIs to ABC	
Renal impairment	95 (83)
Fanconi syndrome	15 (13)
Others	5 (4)
NRTIs before switching to ABC	
Tenofovir disoproxil fumarate	101 (88)
Stavudine	74 (64)
Zidovudine	61 (53)
TDF exposure (days, median, IQR)	
Duration of TDF exposure (days, median (IQR))	1981, 1187.5-2782.0
Duration of TDF usage while CrCl < 60 ml/min (n=97) (days, median (IQR))	287, 98-713
Exposure to other ART associated with renal dysfunction (lifetime)	
Lopinavir/ritonavir (LPV/r)	21 (18)
Indinavir/ritonavir (IDV/r)	2 (2)
Darunavir/ritonavir	2 (2)
History of exposure to nephrotoxic drugs within 6 months prior to ABC initiation	8 (7)
Cardiovascular Risk	
Thai CV risk score (median, IQR)	4.4, 2.8-8.3
History of smoking	3 (3)
Statin use	64 (56)

ABC; Abacavir, NRTIs; Nucleoside reverse transcriptase inhibitors, ART; Anti-retroviral therapy