69. Incidence of metabolic complications among treatment-naïve adults living with HIV-1 randomized to B/F/TAF, DTG/ABC/3TC or DTG+F/TAF after 144 Weeks

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Session: O-15. HIV Co-infections and Co-morbidities

Background. Metabolic comorbidities including diabetes (DM) and dyslipidemia pose challenges to the long-term care of people with HIV (PWH). Incidence of cardiovascular disease and DM are reported at higher rates in PWH than the general population. Obesity is broadly prevalent in both the general population and PWH, and higher body mass index (BMI) can contribute to metabolic complications. Here we present longer-term follow up on incidence of DM, hypertension (HTN), BMI categorical shifts, and lipid changes over 144 weeks of blinded treatment from two trials of PWH initiating antiretroviral therapy.

Methods. We assessed incidence of metabolic complications in adult PWH in Study 1489: bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) vs dolutegravir/abacavir/ lamivudine (DTG/ABC/3TC) and Study 1490: B/F/TAF vs DTG+F/TAF. Treatment-emergent (TE) metabolic comorbidities were defined by standard MedDRA search lists. CDC-defined BMI categories were compared from baseline (BL) to Week 144. Analyses by sex at birth and race were performed, as well as for lipid changes.

Results. Among 1,274 total participants, median (range) age was 33 years (18-77), 90% men, 33% black. In study 1489, BL prevalence of DM and HTN was 4.5 and 12.1% with TE DM and HTN in B/F/TAF being 0.7% and 10%, and for DTG/ABC/3TC 1.3% and 6.9%, respectively. In study 1490, BL prevalence of DM and HTN was 6.8 and 18.8% with TE DM and HTN in B/F/TAF being 2.1 and 5.8%, and for DTG+F/TAF 2.3 and 6.5%, respectively. BMI shift from Normal to Obese: B/F/TAF 0%, DTG/ABC/3TC 3.2%, p=0.12 (1489) (Table 1); B/F/TAF 2.5%, DTG+F/TAF 2.9% p=1.00 (1490) (Table 2). Subgroup analyses by gender/race showed similar findings for TE DM, HTN, and BMI changes. Median changes from BL fasted lipids were small (Table 1).

Table 1§. Studies 1489 and 1490: Metabolic Outcomes from Baseline to Week 144

	B/F/TAF			DTG/ABC/3TC				B/F/TAF			DTG+F/TAF			
	n	n/N	%	n	n/N	%	p-value	n	n/N	%	n	n/N	%	p-value
Treatment-Emergent Diabetes Events*, n= participants	2	2/295	0.7%	4	4/306	1.3%	0.6862	6	6/292	2.1%	7	7/303	2.3%	1.0000
Glucose tolerance impaired	1		0.3%	2		0.7%		2		0.7%	2		0.7%	
Diabetes mellitus	1		0.3%	-				3		1.0%	1		0.3%	
Hyperglycaemia	-			1		0.3%		-			2		0.7%	
Type 2 diabetes mellitus	-			1		0.3%		1		0.3%	1		0.3%	
Blood glucose increased	-			-				-			1		0.3%	
Treatment-Emergent Hypertension Events*, n= participants	28	28/279	10.0%	19	19/274	6.9%	0.2232	15	15/257	5.8%	17	17/263	6.5%	0.8559
Hypertension	20		7.2%	13		4.7%		9		3.5%	15		5.7%	
Blood pressure increased	9		3.2%	4		1.5%		3		1.2%	3		1.1%	
Essential hypertension	1		0.4%	1		0.4%		2		0.8%	-			
Blood pressure diastolic increased	-			1		0.4%		-			-			
Prehypertension	-			-				1		0.4%	-			

Body Mass Index, kg/m2, baseline value and change from baseline, median (Q1, Q3)	B/F/TAF			DTG/ABC/3TC			B/F/TAF			DTG+F/TAF		
	N	median (Q1, Q3)	N	median (Q1, Q3)	p-value	N	median (Q1, Q3)	N	median (Q1, Q3)	p-value
Baseline value, overall	314	25.1 (22.4, 28.7)	315	24.9 (22.5, 29.1)	0.9449	314	25 (22.2, 28.3)	325	24.6 (22.2, 28.0)	0.6927
Week 24, overall	305	0.6 (-0.1, 1.3)	307	0.2 (-0.3, 1.0)	0.0007	301	0.5 (0.0, 1.4)	314	0.6 (0.0, 1.3)	0.6982
Week 48, overall	295	1.0 (0.1, 1.9)	299	0.5 (-0.2, 1.4)	0.0012	292	1.1 (0.2, 1.9)	305	0.9 (0.0, 1.9)	0.6088
Week 96, overall	279	1.1 (0.0, 2.8)	288	0.8 (-0.1, 1.9)	0.0210	271	1.1 (0.0, 2.6)	288	1.3 (0.3, 2.4)	0.5541
Week 144, overall	260	1.3 (0.1, 2.8)	267	1.1 (0.0, 2.5)	0.1874	263	1.4 (0.3, 2.9)	278	1.7 (0.2, 3.1)	0.6976
Baseline value, females	29	29.5 (22.4, 31.9	33	32.7 (25.4, 35.7)	0.2116	37	26.9 (22.4, 30.9)	37	26.7 (22.9, 32.9)	0.8288
Week 144, females	23	1.5 (-0.4, 4.2)	29	2.9 (0.5, 5.0)	0.2770	27	2.6 (0.8, 4.3)	28	1.7 (0.6, 4.1)	0.7163
Baseline value, black race	114	26.6 (22.6, 30.6)	112	26.3 (22.1, 30.7)	0.6975	94	26.1 (22.0, 30.3)	100	25.7 (22.2, 31.4)	0.7030
Week 144, black race	95	1.6 (0.0, 3.0)	96	1.2 (-0.2, 3.1)	0.5611	77	2.1 (0.9, 4.1)	84	2.2 (0.6, 4.0)	0.8870

Fasting lipids, baseline and Week 144 absolute values, mg/dL, median (Q1, Q3)	B/F/TAF		DTG/ABC/3TC		B/F/TAF		DTG+F/TAF	
	Baseline, n=305	Week 144	Baseline, n=305	Week 144	Baseline, n=314	Week 144	Baseline, n=323	Week 144
Total cholesterol	159 (133, 181)	174 (148, 202)	162 (138, 186)	169 (144, 198)	156 (136, 182)	170 (145, 196)	161 (138, 186)	170 (148, 198)
LDL cholesterol	101 (83, 123)	122 (97, 152)	101 (84, 126)	115 (94, 145)	98 (81, 120)	119 (94, 148)	99 (82, 124)	116 (97, 143)
HDL cholesterol	42 (34, 51)	46 (38, 55)	42 (35, 51)	49 (41, 59)	43 (35, 52)	49 (39, 57)	43 (35, 52)	48 (40, 56)
Total HDL cholesterol ratio	3.7 (3.0, 4.7)	3.7 (2.8, 4.6)	3.7 (3.0, 4.6)	3.4 (2.7, 4.6)	3.7 (3.0, 4.5)	3.6 (2.9, 4.6)	3.7 (3.1, 4.5)	3.5 (2.8, 4.3)

*Excluding individuals with baseline diagnosis of diabetes and/or hypertension
§P-values were from the 2-sided Wilcoxon rank sum test to compare treatment groups

Table 2±. Shift Table of BMI Category at Week 144 by Baseline BMI Category – Overall

Conclusion. Through over 144 weeks of follow up, PWH randomized to initiate B/F/TAF, DTG/ABC/3TC or DTG+F/TAF had low rates of incident DM or HTN-related AEs, with no statistically significant differences by treatment group. BMI changes/categorical shifts from BL did not significantly differ by regimen, and no clinically significant change or difference by regimen in lipids were observed. While data are limited by three years of follow up, they are strengthened by randomized study design of three widely used initial ART regimens.

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70. Changes in Invasive Pneumococcal Disease among Adults Living with HIV Following Introduction of 13-Valent Pneumococcal Conjugate Vaccine, 2008–2018

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Session: O-15. HIV Co-infections and Co-morbidities

Background. People living with HIV (PLHIV) are at increased risk of invasive pneumococcal disease (IPD). The 13-valent pneumococcal conjugate vaccine (PCV13) was recommended for children in 2010, and for immunocompromised adults (including PLHIV) in series with 23-valent polysaccharide vaccine (PPSV23) in 2012. We evaluated changes in IPD incidence in adults ≥19 years old by HIV status after PCV13 introduction and proportion of remaining IPD due to serotypes included in the 15-(PCV15) and 20-valent (PCV20) conjugate vaccines expected to be licensed in 2021.

Methods. IPD cases were identified through CDC's Active Bacterial Core surveillance (ABCs). HIV status was obtained from medical records. Isolates were serotyped by Quellung reaction, or whole-genome sequencing and grouped into PCV13-types, PPV11-types (unique to PPSV23), or non-vaccine types. We estimated IPD incidence (cases per 100,000 people) using national projections of ABCs cases as numerators and national case-based HIV surveillance (PLHIV) or US census data (non-PLHIV) as denominators. We compared IPD incidence in 2011–12 and 2017–18 to pre-PCV13 baseline (2008–09) by serotype groups. We assessed the proportion of IPD due to serotypes included in PCV15 and PCV20.

Results. Overall IPD incidence at baseline was 306.7 for PLHIV and 15.2 for non-PLHIV. From baseline to 2017–18, IPD incidence declined in PLHIV (-40.3%; 95% CI: -47.7, -32.3%) and non-PLHIV (-28.2%; 95% CI: -30.9, -25.5%). The largest reductions were in PCV13-type IPD during both periods (-44.2% for PLHIV and -42.2% for non-PLHIV in 2011–12; -72.5% for PLHIV and -62.2% for non-PLHIV in 2017–18) compared to baseline (Figures 1, 2). In 2017–2018, overall IPD and PCV13-type rates were 16.8 (95% CI: 15.1, 18.5) and 12.6 (95% CI: 9.9, 15.3) times as high in