Results. 5% of participants had < 90% adherence in both treatment arms. Baseline VL and CD4+ cell counts were similar across adherence categories. VR was lower in the < 90% adherence group than the ≥ 90% group, but not different between the 2 treatment arms within the same adherence category: In the low adherence group, DTG+3TC VR was 69% compared to 65% in DTG+TDF/FTC arm by Snapshot and 91% and 85% respectively by last on treatment VL analysis (Table).

Table.

Table. Virologic Response (Using Snapshot at Week 48 or Last on Treatment VL) by Adherence Category (ITT-E Population[a])

Efficacy endpoint	Adherence level category	DTG + 3TC n/N (%; 95% CI)	DTG + TDF/FTC n/N (%; 95% CI)	Treatment difference[b] (%; 95% CI)
HIV-1 RNA <50 c/mL (Snapshot)	≥90%	631/679 (93%; 90.7-94.7)	647/677 (96%; 93.7-97.0)	−2.6% (−7.9%, 2.7%)
	<90%	24/35 (69%; 50.7-83.1)	22/34 (65%; 46.5-80.3)	3.9% (−20.4%, 26.2%)
HIV-1 RNA <50 c/mL (last on treatment VL)	≥90%	661/679 (97%; 95.8-98.4)	668/677 (99%; 97.5-99.4)	−1.3% (−6.7%, 4.1%)
	<90%	32/35 (91%; 76.9-98.2)	29/34 (85%; 68.9-95.0)	6.1% (−17.6%, 28.8%)

CI, confidence interval; DTG, dolutegravir; FTC, emtricitabine; ITT-E, intention to treat–exposed; 3TC, lamivudine; TDF, tenofovir disoproxil fumarate; VL, viral load. [a]Excluding 2 and 6 participants in the DTG + 3TC and the DTG + TDF/FTC treatment arms, respectively, for whom no adherence could be derived. [b]DTG + 3TC response rate - DTG + TDF/FTC response rate.

Conclusion. In the GEMINI studies, a lower Week 48 VR was observed in participants with < 90% adherence, but the impact of lower adherence on VR was similar in the DTG+3TC compared with DTG+TDF/FTC arms. One limitation of the analysis is the small number of participants in the lower adherence subgroup. However, the results add further information about the robustness of DTG+3TC compared to 3-drug DTG-containing regimens and may suggest similar regimen forgiveness.

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1025. Integrating buprenorphine into an urban HIV primary care practice: Outcomes on viral load suppression and opioid use

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Session: P-47. HIV: Treatment

Background. Opioid use disorder (OUD) is a correlate of poorer HIV outcomes among people with HIV (PWH). Research has shown promising results for buprenorphine (BUP), a medication for OUD, integrated into HIV primary care. In this study, we explored the effect of BUP on HIV outcomes in a cohort of PWH with OUD in Newark, New Jersey.

Methods. We performed a retrospective chart review of PWH on BUP attending the Rutgers NJMS Infectious Diseases Practice from January 2017 to June 2019 (n=91, median age 56, 59% male, 84% Black, median follow-up 1.5 years). Outcomes were suppressed HIV viral load measurements (VLS) or urine drug screening results (UDS). We analyzed data using descriptive statistics and multivariate logistic regression, which modeled associations of VLS or UDS with demographic, comorbid (substance use, chronic pain, HCV, psychiatric diagnosis), and social (insurance, employment, housing) factors. Results presented as odds ratio; 95% confidence interval.

Results. 55% (n=46) of patients demonstrated BUP adherence (> 50% positivity on serial UDS) and 61% (n=51) had ongoing opioid use. Patients with a UDS positive for opioids (primarily opiates) were more likely to have other substance co-positivity on UDS (5.4; 4.0-7.3, p < 0.001), to be employed (5.4; 2.7-10.7, p=0.01), and enrolled in Medicaid (4.6; 2.5-8.5, p=0.01); and less likely to have BUP positive UDS (0.067; 0.050-0.088, p < 0.001). Conversely, BUP positive UDS was negatively associated with the presence of other substances (0.55; 0.44-0.70, p=0.01) and history of alcohol use (0.56; 0.40-0.79, p=0.05), controlling for concurrent opioid positivity and baseline VLS. At baseline, 39% (n=32) of patients did not have VLS; at 1 year follow-up, one-third (n=11) achieved new-onset suppression. VLS during follow-up was positively associated with BUP adherence (2.9; 1.2-7.1, p=0.02) and VLS at baseline (17.0; 10.4-27.8, p < 0.001), and negatively associated with housing insecurity (0.28; 0.15-0.52, p=0.04).

Conclusion. Integration of BUP for OUD into HIV primary care led to a decrease in opioid use and improved outcomes in HIV care. Multidisciplinary approaches addressing other substance use and social services may help achieve even greater progress in ending the dual epidemics of HIV and OUD.

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1026. Is Empiric Coverage Necessary? Incidence of Pseudomonas aeruginosa and Methicillin-Resistant Staphylococcus aureus in Foot Infections

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Session: P-47. HIV: Treatment

Background. Empiric antibiotics for foot infections often include coverage of *Pseudomonas aeruginosa* (PA) and Methicillin-resistant *Staphylococcus aureus* (MRSA) due to their presumed frequency and ability to cause severe infection. The purpose of this study was to: 1) determine the incidence of PA and MRSA in foot infections; 2) identify variables associated with the presence of PA or MRSA; and 3) examine empiric antibiotic trends for foot infections to determine if empiric coverage of PA and MRSA is warranted.

Methods. Retrospective study of foot infections at five large urban hospitals in San Diego during 2018. Data were collected from the medical records including demographics, host factors, laboratory data, pathology and imaging data, culture results, and empiric antibiotics. Patients with a foot infection treated as an inpatient in our healthcare system who had a culture collected were included.

Results. 310 patients with foot infections were included. Mean age was 61.6 years; 220 (71%) were male; 248 (80%) had diabetes; 40 (13%) had end-stage renal disease (ESRD), and 122 (39%) had peripheral arterial disease (PAD). PA was present in 28 (9%) cases. No patient had a positive blood culture for PA. MRSA was present in 55 (18%) cases. Only one patient had a positive blood culture for MRSA. On univariate analysis, wound location not in the forefoot (p=0.047) and presence of PAD (p=0.048) were associated with PA. These failed to remain significant in multivariate analysis (OR=0.42, p=0.074 and OR=2.54, p=0.0504, respectively). Factors associated with MRSA included shallower depth of wound (OR=0.36; p=0.043). 199/310 patients (64%) received empiric antibiotic coverage for PA while 262/310 patients (85%) received empiric MRSA coverage. Of those who received empiric anti-PA coverage, 174 were overtreated (87%). Of those who received empiric anti-MRSA coverage, 218 (83%) were overtreated.

Conclusion. The incidence of PA in foot infections was overall low, and none had positive blood cultures. MRSA was more often present, however, most patients did not have bacteremia or severe infections. In our study, the majority of empiric anti-PA, as well as anti-MRSA, antibiotic coverage for foot infections was unnecessary questioning the need for upfront, empiric coverage for these pathogens in foot infections.

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1027. Long-Term Efficacy, Safety, and Durability of Ibalizumab-Based Regimens in Subgroup of TMB-202 Participants

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Session: P-47. HIV: Treatment

Background. Third line antiretroviral regimens have been associated with suboptimal virologic suppression, due to drug cross-resistance and regimen complexity. Yet, in treatment-experienced (TE) HIV patients, ART durability is essential for preventing further resistance and decreasing HIV-associated morbidity and mortality. Ibalizumab (IBA), the first long-acting, post-attachment inhibitor approved to treat multi-drug resistant (MDR) HIV, may support regimen durability given its directly observed administration. We analyzed the safety, efficacy, and durability of response in 12 patients who started IBA in a Phase 2b study.

Methods. In TMB-202, 113 patients with MDR HIV received either 2000 mg IBA every 4 weeks (n=54) or 800 mg IBA every 2 weeks (n=59) for 24 weeks with an optimized background regimen (OBR). Of 96 patients who completed TMB-202, 56 transferred into an investigator-sponsored investigational new drug protocol and 12 later moved onto an expanded access protocol, TMB-311, where efficacy and safety were monitored until IBA was commercially available (approval 2018).

Results. Baseline median viral load (VL) and CD4 count for the 12 patients were 4.4 log$_{10}$ copies/mL (c/mL) and 135 cells/mL, respectively. The median duration of HIV infection was 22 years (range 18-25). At the completion of TMB-202 11/12 achieved virologic suppression (VL < 200 c/mL) and 8/12 had VL < 50 c/mL. All 12 patients were suppressed (VL < 50 c/mL) at their last TMB-311 visit. Patients gained an average of 99 CD4 cells/mL relative to baseline. There were no treatment-emergent adverse events (TEAE) or therapy discontinuations related to IBA during follow-up. Two patients died from unrelated causes. Overall, the 12 patients remained on IBA for an

average of 8.9 years (range 8-9.5), during which 8/12 did not require addition of new ARVs to their OBR to maintain suppression.

Figure 1: duration of ibalizumab-based regimen is displayed for the 12 patients. Grey bars represent patients with no addition of new ARVs to OBR. Black bars represent patients with an addition to OBR. Asterisks represent addition of ritonavir only.
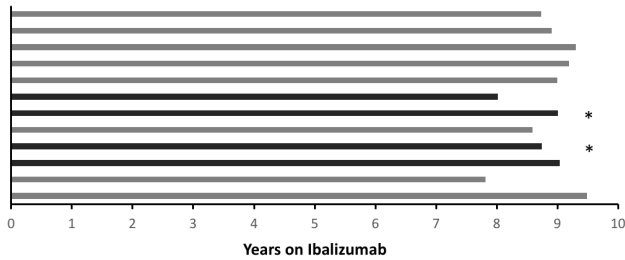
Conclusion. Data from 12 patients who received IBA for an average of 9 years validate the long-term efficacy and safety of IBA in TE patients. Importantly, for most patients, the durability of virologic response was maintained with minimal adjustments to the OBR. Altogether, these data demonstrate the contribution of IBA towards durable viral suppression in TE HIV patients with limited therapeutic options.

1028. Long-term Follow-up After a Switch to Bictegravir, Emtricitabine, Tenofovir Alafenamide from Dolutegravir, Abacavir, Lamivudine

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Session: P-47. HIV: Treatment

Background. Bictegravir, emtricitabine and tenofovir alafenamide (B/F/TAF) is a guidelines-recommended single-tablet regimen (STR) for people living with HIV-1 (PLWH). Week (W) 48 primary endpoint results of this phase 3 study switching to B/F/TAF from dolutegravir (DTG), abacavir (ABC) and lamivudine (3TC) established the safety and efficacy of B/F/TAF. Here we report outcomes from an open-label (OL) extension of B/F/TAF.

Methods. Adults virologically suppressed on DTG, ABC, and 3TC were randomized 1:1 to switch to B/F/TAF once daily or continue their current regimen as a STR in a double blind (DB) manner. Unblinding occurred after the W48 primary endpoint, then participants received B/F/TAF in an OL extension while transitioning off the study. All participants who received B/F/TAF in the DB or OL phases are included in analyses. Efficacy was assessed as the proportion with HIV-1 RNA < 50 copies/mL at each study visit using missing=excluded (M=E) analysis, efficacy in in subgroups with pre-existing resistance was assessed using last observation carried forward. Safety was assessed by adverse events (AEs) and laboratory results.

Results. 563 participants were randomized and treated (282 B/F/TAF, 281 ABC/DTG/3TC); 524 (93%) completed the DB phase and received OL B/F/TAF; a total of 547 participants received B/F/TAF in DB and/or OL phases: 11% women, 21% Black, median age 47 yrs (range 21, 71). The median duration of B/F/TAF was 96 weeks (IQR 49-119). HIV-1 RNA < 50 c/mL was maintained in 99-100% at all timepoints (M=E) through a maximum of 168 weeks, including high efficacy in those with archived resistance (Table 1). No participant developed resistance to B/F/TAF. Study drug-related AEs occurred in 7% on B/F/TAF; most were grade 1; the most common was headache (1.6%). 7 (1%) participants had an AE leading to premature study drug discontinuation, only 1, headache, occurred in the OL phase. Estimated GFR and lipids were mostly stable with slightly increased LDL at W96; weight changes are noted at W48 and W96. (Table 2).

Table 1.

Table 1. Preexisting Resistance and B/F/TAF Efficacy

% (n/n)	All B/F/TAF	HIV-1 RNA < 50 copies/mL at Last Study Visit[b]
≥1 HIV-1 RNA measurement post B/F/TAF switch	545	98% (535/545)
Baseline resistance data available[a]	96% (522/545)	98% (512/522)
No primary resistance (PR, RT, IN)	69% (361/522)	98% (353/361)
Any primary resistance (PR, RT, IN)	31% (161/522)	99% (159/161)
NRTI resistance	9% (48/522)	98% (47/48)
M184V/I	3% (17/522)	100% (17/17)
Any TAM	7% (36/522)	97% (35/36)
1-2 TAMs	5% (28/522)	100% (28/28)
≥3 TAMs	2% (8/522)	88% (7/8)
NNRTI resistance	17% (88/522)	98% (86/88)
PI resistance	10% (54/522)	98% (53/54)
INSTI resistance	3% (16/522)	100% (16/16)
T97A	2% (12/522)	100% (12/12)

a. Baseline data derived from cumulative historical and/or proviral genotypes
b. Outcomes determined by last on-treatment observation carried forward analysis through the end of study

Table 2.

Table 2. Changes from baseline after switching to B/F/TAF

	All B/F/TAF (n=547)	DTG/ABC/3TC* (n=281)
Median (Q1, Q3) change in eGFR, mL/min		
Week 48 (n=482)	2 (-5, 10)	-2 (-9, 5)
Week 96 (n=281)	2 (-5, 9)	--
Median (Q1, Q3) change in fasting lipids Week 48 (n=468)		
Total cholesterol, mg/dL	-3 (-18, 13)	2 (-17, 18)
LDL cholesterol, mg/dL	2 (-12, 18)	2 (-14, 14)
HDL cholesterol, mg/dL	-1 (-6, 3)	0 (-4, 6)
Total Cholesterol:HDL ratio	0.0 (-0.4, 0.4)	0.0 (-0.5, 0.4)
Triglycerides, mg/dL	-3 (-31, 24)	3 (-21, 30)
Median (Q1, Q3) change in fasting lipids Week 96 (n=269)		
Total cholesterol, mg/dL	2 (-13, 17)	--
LDL cholesterol, mg/dL	12 (-4, 27)	--
HDL cholesterol, mg/dL	-1 (-7, 4)	--
Total Cholesterol:HDL ratio	0.1 (-0.3, 0.6)	--
Triglycerides, mg/dL	1 (-31, 29)	--
Median (Q1, Q3) change in body weight, kg		
Week 48 (n=482)	1.5 (-0.4, 3.8)	0.8 (-1.5, 2.7)
Week 96 (n=282)	2.3 (0.0, 5.1)	--

*Data from participants randomized to DTG/ABC/3TC is from the double-blind phase

Conclusion. Extended follow-up to the study of switching to B/F/TAF from DTG/ABC/3TC, demonstrates continued high rates of virologic suppression with no resistance and excellent safety and tolerability of B/F/TAF through a maximum of 168 weeks for treatment of PLWH.