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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 antiviral 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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Session: P-47. HIV: Treatment

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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Session: P-47. HIV: Treatment

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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Session: P-47. HIV: Treatment

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 ≤ 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: ≥ 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.

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