2493. Real-World Utilization of Ibalizumab (IBA) Without an Optimized Background Regimen (OBT)

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Background. It is difficult to treat multidrug-resistant (MDR) human immuno-deficiency virus (HIV). Trogarzo® (ibalizumab) a novel monoclonal antibody was approved in 2018 for heavily treatment-experienced HIV patients. Data support IBA use with at least one fully active agent, an OBR. Real-world IBA data are lacking. We report a successful case of reaching and maintaining suppression with IBA in a patient without an OBR.

Methods. Mutations were reviewed for the patient, Table 1, and evaluated for treatment. The patient is a 52- year old male, diagnosed in 1994, with MDR HIV secondary to non-adherence. Upon re-presenting to care, the patient was non-compliant with ART. Genotypic interpretation via the Stanford/ANRS algorithm was performed and interpreted, resulting in the addition of IBA intravenous administration every other week. IBA was obtained through patient assistance and costs were covered by the institution for infusion.

Results. Evaluation of the resistance profile indicated varying resistance to all available ART. More specifically, high-level resistance to all FDA-approved INSTIs, PIs, and low to high-level resistance to all NNRTIs and NRTIs. Table 2 outlines the ART history and viral load (VL) trends. The patient was initiated on daruanvir/ritonavir twice daily, etravirine twice daily, emtricitabine/tenofovir alafenamide and did not reach suppression. IBA was added off-label to a failing regimen. The patient reached VS (VL < 200 copies/mL) at Week 4 and has had an undetectable VL for 8 weeks. Notably his CD4 count has risen to 46, first detectable number since re-presenting to care.

Conclusion. We describe a heavily treatment experienced patient with an MDR HIV virus who achieved an undetectable VL without an OBT and the addition of intravenous IBA. Fostemsavir, was utilized in IBA's phase III trial for similar patients, however, it is not currently FDA-approved nor available. Further data are needed to ensure continued susceptibility to IBA without an OBT. This patient required high-level coordination to reach each visit and receive this therapy alongside his oral agents. We conclude, IBA has allowed this patient to reach and maintain VS.

Drug Class	Mutations
Integrase Inhibitors	T97A, E138T, G140S, Q148H, G163T
NNRTIs/NRTIs	M41L, A98G, M184V, T215Y, K101E
Protease Inhibitors	L10F, K20T, V32I, L33F, M36I, M46I, I47V, I54L, Q58E, I84V, K20T

Plasma HIV RNA
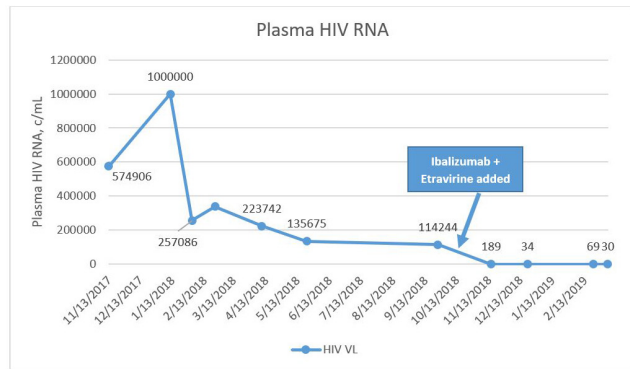
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2494. Real-World Use of Ibalizumab in Physician Office Infusion Centers (POICs)

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Background. Ibalizumab-uiyk (IBA) was recently approved for the treatment of multi-drug-resistant HIV-1 infection in patients (pts) failing other antiretroviral regimens. Clinical trial data demonstrated a decrease in HIV-1 viral load in 83% and 43% of patients (*n* = 40) receiving IBA for 2 and 25 weeks (weeks), respectively. Real-world post marketing data are needed. This pilot study reports the experience of IBA utilization in POICs.

Methods. Medical records of patients receiving intravenous IBA from approval through April 2019 were reviewed. Data collected include demographics, infection and treatment history, IBA regimen and adverse events. Plasma HIV-1 RNA viral load

(log$_{10}$ copies/mL) and CD4 count (cells/µL) were collected at baseline and as available during therapy. Based on available follow-up (FU) labs, response was assessed at 4–10 weeks (FU 1), 14–22 weeks (FU 2), and 24–37 weeks (FU 3).

Results. Nine patients (mean age: 48 ± 11 years, 67% male) from 7 POICs received IBA for a median duration of 33 weeks (range 4–43). Median length of HIV-1 diagnosis was 22 years (range 8–25). Resistance to ≥1 drug in at least 3 drug classes was reported in 56%. All patients received at least one concurrent anti-retroviral agent. IBA was initiated at 2000 mg followed by 800 mg every 2 weeks. All patients received infusions as scheduled (151 total infusions) except for one requiring a second loading dose. Baseline mean CD4 count and viral load were 49 cells/µL and 4.9 log$_{10}$ copies/mL, respectively. Labs obtained at FU 1 indicated a decrease in viral load of at least 0.5 log$_{10}$ copies/mL in 6/8 patients (75%); a mean reduction of 2.1 ± 1.8 log$_{10}$ copies/mL (Table 1). Mean HIV-1 titers available for patients at FU 2 (*n* = 6) and FU 3 (*n* = 7) were 3.1 ± 2.0 and 3.2 ± 2.6 log$_{10}$ copies/mL, respectively. Mean CD4 counts were 65 ± 57 cells/µL at FU 1, 96 ± 61 cells/µL at FU 2 and 88 ± 82 cells/µL at FU 3. Adverse events were reported in 8 patients (89%), most common itching/rash, diarrhea and abdominal pain. None resulted in discontinuation of IBA.

Conclusion. This study confirms the antiviral activity of IBA in patients with advanced HIV-1 infection in the real-world setting. We observed well-tolerated therapy with an early reduction in HIV-1 viral load of 75%, followed by a 43% reduction ≥24 weeks, consistent with the clinical trial.

Table 1. Time-dependent Effect of Ibalizumab on Viral Load and CD4 Count

Patient ID	Length on Ibalizumab (to-date)	Viral Load/ CD4 Count	Baseline	Follow-Up 1 (week 4 to 10)	Follow-Up 2 (week 14 to 22)	Follow-Up 3 (week 24 to 37)
#1	45 weeks	log$_{10}$ copies/mL/	5.4	5.1	5.2	5.5
		cells/µL	50	79	88	95
#2	42 weeks	log$_{10}$ copies/mL/	3.1	1.9	1.9	not detected
		cells/µL	205	169	165	144
#3	41 weeks	log$_{10}$ copies/mL/	4.6	4.6	4.5	4.5
		cells/µL	15	24	11	10
#4	38 weeks	log$_{10}$ copies/mL/	5.3	n/a	n/a	5.5
		cells/µL	47	n/a	n/a	3
#5	33 weeks	log$_{10}$ copies/mL/	4.9	1.5	not detected	not detected
		cells/µL	54	98	116	115
#6	31 weeks	log$_{10}$ copies/mL/	5.4	1.9	2.2	1.6
		cells/µL	60	102	153	225
#7	26 weeks	log$_{10}$ copies/mL/	5.0	2.4	4.9	5.3
		cells/µL	4	11	41	25
#8	8 weeks	log$_{10}$ copies/mL/	6.0	4.9	pending	pending
		cells/µL	0	0	pending	pending
#9	4 weeks	log$_{10}$ copies/mL/	4.9	not detected	expired	
		cells/µL	2	36		

Abbreviations: n/a; labs not available.

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2495. Pharmacokinetics of Cabotegravir (CAB) and Rilpivirine (RPV) Long-Acting (LA) Injectables in HIV-infected Individuals through 48 Weeks in the FLAIR and ATLAS Phase 3 Studies

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Background. Monthly injectable CAB LA + RPV LA was noninferior to daily oral 3-drug antiretroviral therapy in HIV-1 virologically suppressed adults. CAB and RPV pharmacokinetics (PK) were assessed during the 48 Week maintenance period of the ATLAS and FLAIR Phase 3 studies.

Methods. Patients received oral CAB 30 mg + RPV 25 mg once daily for 4 weeks to assess individual tolerability prior to intramuscular (IM) injections of CAB LA 600 mg + RPV LA 900 mg followed by CAB LA 400 mg + RPV LA 600 mg every 4 weeks. Plasma CAB and RPV concentrations were measured pre-and post-dose at select visits using validated analytical methods.

Results. Baseline demographics for the pooled randomized ATLAS and FLAIR population (*n* = 591, LA arms) were: median age 38 years, 27% female, 18% African American, median BMI 25 kg/m^2 (range: 15 – 51). CAB and RPV plasma concentrations at select visits are summarized in the table. After initial IM doses, mean CAB and RPV troughs were well above their respective in vitro PA-IC90 values (CAB, 0.166 µg/mL; RPV 12 ng/mL). At Week 48, mean CAB troughs were 17x PA-IC90 and between oral CAB 10–30 mg exposures. Similarly, mean RPV troughs were 7x PA-IC90 and remained within the exposure range following oral RPV 25 mg once daily. 80% of RPV steady-state was achieved by Week 48 and 100% for CAB by Week 44. Initial CAB concentrations in females and those with BMI ≥30 kg/m^2 were lower due to slower absorption but this difference resolved by Week 48. For RPV, there was no absorption difference by gender or BMI.

Conclusion. CAB and RPV PK were consistent between studies achieving therapeutic concentrations within the first dosing interval that steadily increased over time through Week 48, for both males and females and irrespective of BMI. CAB LA + RPV LA provided compatible PK profiles following monthly IM dosing in a diverse patient population through 48 weeks.

Geometric mean [95%CI] plasma CAB and RPV Ctau at select visits				
	CAB (mcg/mL)		RPV (ng/mL)	
Visit	ATLAS	FLAIR	ATLAS	FLAIR
Week 4b (after last oral dose)	4.69 [4.47, 4.92]	5.22 [4.88, 5.57]	75.4 [70.8, 80.2]	79.1 [74.1, 84.3]
Week 8 (4 weeks after initial IM dose)	1.23 [1.13, 1.33]	1.56 [1.45, 1.68]	38.6 [36.0, 41.4]	41.2 [38.7, 43.9]
Week 48 (4 weeks after monthly IM dose)	2.84 [2.68, 3.01]	3.13 [2.95, 3.33]	90.3 [84.9, 96.0]	82.4 [77.8, 87.2]

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2496. Qualitative Thematic Analysis of Social Media Data to Assess Perceptions of Daily Oral and Long-Acting Injectable Antiretroviral Treatment among People Living with HIV

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Background. Current HIV treatment options consist of daily oral antiretroviral therapies (ART). A long-acting injectable HIV treatment is in development for monthly or every other month administration. Patient preferences for ART are important to understand and can impact retention in care, adherence and outcomes. The purpose of this study was to obtain and analyze patient perceptions of oral and injectable ART using a novel approach.

Methods. Qualitative thematic analysis was conducted to examine online discussion threads posted by people living with HIV (PLHIV) in POZ Community Forums from 2013 to 2018. Perceptions of ART were analyzed using keywords (e.g., dose, pill, daily, long-acting, injection, monthly, cabotegravir). Relevant threads were extracted, reviewed and coded using qualitative data analysis software (ATLAS.ti.8).

Results. Analyses identified 684 relevant discussion threads including 2,629 coded quotations posted by 568 PLHIV. Oral ART (2,517 quotations) was discussed more frequently than injectable ART (112). Positive statements on oral ART commonly mentioned the small number of pills (278), dose frequency (248), ease of scheduling (154), and ease-of-use (146). PLHIV also noted disadvantages of oral ART including negative emotional impact (179), difficulty with medication access (137), scheduling (131), and treatment adherence (128). Among the PLHIV discussing injectable ART, common positive comments focused on less frequent administration (34), emotional benefits of not taking a daily pill (7), potential benefits for adherence (6), overall convenience (6), and benefits for traveling (6). Some quotations (10) perceived the frequency of injections negatively, and others had negative perceptions of needles (8) or appointments required to receive injections (8).

Conclusion. ART was frequently discussed among PLHIV on this online forum. This innovative approach for obtaining and analyzing unsolicited comments revealed that while many PLHIV expressed positive views about their daily oral regimen, others perceived inconveniences and challenges. Among PLHIV who were aware of a possible long-acting injectable treatment, many viewed this potential new option as a convenient alternative with the potential to improve adherence.

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2497. Women's Perspectives on and Experiences with Long-acting Injectable Antiretroviral Therapy in the United States and Spain: the Potential Role of Gender in Patient Preferences

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Background. Adherence to antiretroviral therapy (ART) to treat HIV remains a critical global health challenge given its relationship with individual health outcomes and population-level transmission. Given barriers associated with oral ART adherence, and considerations of patients' preferences, long-acting injectable (LA) ART (cabotegravir + rilpivirine) is under development and has been shown to be non-inferior to daily oral ART in Phase III trials. While most of the trial participants have been men, as LA ART gets closer to becoming available for routine clinical use, it is critical to understand how this option is perceived by women.

Methods. We conducted in-depth interviews with 67 individuals, 53 people living with HIV (PLHIV) and 14 healthcare providers, in 11 sites in the United States and Spain participating in Phase III LA ART trials (ATLAS, ATLAS 2-M and FLAIR). Twenty percent (10/53) of trial participants interviewed were women. Interviews explored patient and provider perspectives and experiences with LA ART, and appropriate candidates and recommendations to support use. Interviews were audio-recorded, transcribed and coded using thematic content analysis.

Results. Overall, several salient themes emerged regarding participant's generally positive experiences transitioning from daily oral ART to injectable ART including: the importance of the clinical efficacy of LA ART, the ability to learn to manage injection side-effects over time, and the "freedom" reportedly afforded by LA ART logistically and psychosocially. Women interviewed shared many of the aforementioned positive perceptions of LA ART but also had some unique perspectives. Female participants discussed how LA ART was easier to integrate into their daily lives including managing their multiple roles and responsibilities, which often involved working full-time and taking care of themselves as well as their family and children.

Conclusion. Similar to all participants, female participants had generally positive views of LA ART. However, the gendered nature of their daily lives also led to some unique perspectives on why and how they were satisfied with LA ART that merits further exploration in future research.

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2498. Perceptions of Injectable Antiretrovirals in an Urban HIV Clinic

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Background. Although new injectable antiretrovirals (ARV) for HIV may soon be available, there is little research on patient preferences. We examined perceptions of injectable ARV among persons living with HIV (PLWH).

Methods. This cross-sectional study was conducted among PLWH presenting for an appointment at TempleHealth in Philadelphia, PA between March 11 and April 18, 2019. Respondents completed a self-administered survey comprising 29 questions about socio-demographic data, current ARV, and preferences regarding injectable ARV therapies. Responses were recorded on a 10-point Likert scale, on which responses in the 1–5 range were defined as unlikely and 6–10 range as likely to choose injectable ARV. The primary endpoint was to describe factors associated with likely vs. unlikely uptake of injectable ARV. Responses between groups were compared with Chi-square or Wilcoxon rank-sum tests.

Results. 171 patients completed a survey with a 56% response rate. Demographics were 60% male, 70% African American, 33% LGBQ-identifying, 2% transgender, with a mean age of 48 ± 13 years. Percentages of likely uptake (55%, $n = 94$) and unlikely uptake (45%, $n = 77$) were similar. Median likelihood was 7 (IQR 7–10) and varied from likely (10, IQR 8–10) and unlikely (1, IQR 1–5) cohorts. There were no differences in overall likelihood based on current number of pills or pill frequency ($P > 0.05$). A likelihood trend was found among patients who missed one or more doses per week, however current adherence was not significant (p = 0.06). Likelihood of uptake means increased as the frequency of administration decreased: 1-week (5.7 ± 3.7), 2-week (5.9 ± 3.7), 1-month (7.3 ± 3.5), 2-month (7.3 ± 3.6), and 3-month (7.7 ± 3.4). Likelihood of uptake decreased as duration of a potential injection site reaction increased: 1 day (6.2 ± 3.5), 2–3 days (4.6 ± 3.3), 4–6 days (3.6 ± 3.1), 7 days or longer (3.0 ± 3.2). Respondents preferred their doctor's office (60%) over self-injection (23%), assisted injection at home (11%), pharmacy (4%), or special injection center (2%) for administration setting.

Conclusion. Our study indicates that availability of injectable administration has potential to find acceptance among PLWH.

Disclosures. All authors: No reported disclosures.

2499. Perceptions of and Preferences for Oral or Long-Acting Injectable Antiretroviral Treatment Regimens in the United States and Canada

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Background. Antiretroviral treatment (ART) for patients living with HIV (PLHIV) has improved greatly, however, challenges with daily oral dosing remain. New ART options with reduced dosing frequency and innovative delivery methods may help address these challenges. This study assesses patient and physician satisfaction with current treatments and preferences for switching to a monthly or every other month long-acting injectable (LAI) ART.

Methods. This is a cross-sectional online survey of PLHIV and physicians treating PLHIV in United States and Canada. A literature review, clinical expert input, and qualitative and quantitative pilots informed survey design. Eligible PLHIV were on ART for ≥ 6 months and virally suppressed (self-reported). Survey questions for patients evaluate satisfaction and adherence to current ART. Treatment preferences are assessed using a discrete choice experiment (DCE), where respondents choose between