Identifying and Characterizing People With HIV Who Are Virologically Suppressed and Receiving Complex Regimens in Spain: The CoRIS Cohort

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GS-US-621-7776

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Conclusions

- This is the first study to identify and characterize people with HIV who are virologically suppressed, treatment experienced, and receiving a complex regimen in Europe
- In a cross-sectional analysis of the CoRIS cohort, 855 of 7,409 people with HIV (11.5%) who were virologically suppressed and treatment experienced were receiving a complex regimen
- Although this population had durable virologic suppression and preserved immune function, many remained on antiretroviral therapies (ARTs) requiring multiple tablets, twice-daily dosing, or boosted protease inhibitor (bPI)–containing regimens that are clinically challenging to manage due to metabolic adverse events and drug-drug interactions
- These findings support continued assessment of individualized needs of people with HIV to optimize HIV treatment
- People with HIV who are virologically suppressed, treatment experienced, and receiving a complex regimen may be candidates for treatment optimization strategies such as once-daily bictegravir/lenacapavir (BIC/LEN)
- **Ongoing regimen complexity may signal a need for treatment optimization, but most participants were clinically stable**

Plain Language Summary

- Modern human immunodeficiency virus (HIV) treatment is often simple and may involve taking one pill per day. However, some people need more complex treatments to keep their HIV under control and stay healthy
- In this study of the CoRIS cohort in Spain, about 1 in 9 people with HIV whose HIV was under control and who had previously used other HIV treatments were receiving a complex HIV regimen
- Many people kept their HIV under control for several years while taking these regimens. However, the treatments often required more than one tablet, taking medicine twice a day, and were more likely to interact with other medicines and have side effects
- These findings show that HIV treatment should be tailored to each person's needs. They also show that some people may benefit from additional treatment options, even when their HIV is under control
- BIC/LEN is a once-daily treatment option that may help make HIV treatment easier for some people receiving more complex HIV treatments

Introduction

- HIV treatment goals increasingly extend beyond maintaining viral suppression to include long-term safety, tolerability, optimization, and quality of life[1]
- In Spain, an estimated 160,000 people are living with HIV.[2] As effective ART has increased life expectancy, the HIV population is aging alongside the broader Spanish population, of whom 21.1% are aged ≥65 years[3]
- As people with HIV age, the prevalence of comorbid conditions and concomitant medication use increases, resulting in a greater risk of drug-drug interactions and a higher overall treatment burden[4]
- Despite modern advances in ART, with daily single tablet regimens (STRs), some people with HIV are receiving complex regimens due to drug resistance, intolerance, toxicity, drug-drug interactions, or contraindications[5]
- ARTISTRY-1, a phase 2/3 clinical trial, demonstrated that switching virologically suppressed people with HIV from a complex regimen to once-daily BIC/LEN maintained viral suppression through Week 48 with noninferior efficacy versus continued complex therapy, supporting FDA approval of BIC/LEN and increasing interest in understanding populations receiving complex regimens in real world settings[6]
- In a retrospective U.S. real-world study of electronic medical records from the Trio Health HIV Network, Sax et al identified 3,320 (8%) virologically suppressed individuals receiving complex regimens among 43,236 ART records[7]
- Real-world studies describing the population size, clinical profile, and treatment patterns of people with HIV who are receiving complex regimens in Europe remain limited; therefore, we aimed to quantify and characterize this population

Objective

- To identify and characterize people with HIV in Cohorte de la Red de Investigación en Sida (CoRIS) who were virologically suppressed, treatment experienced, and receiving complex antiretroviral regimens

Methods

Data Source

- CoRIS is an ongoing, multicenter prospective cohort of adults with newly diagnosed HIV at enrollment, including >20,000 participants recruited from approximately 51 centers across 15 of Spain's 17 autonomous regions[8]
- Since 2004, CoRIS has collected longitudinal clinical, virologic, immunologic, and treatment data, enabling evaluation of long-term HIV disease progression, treatment utilization, and outcomes in routine clinical care[8,9]

Design and Population

- We conducted a cross-sectional analysis within CoRIS on 1 January 2022 (index)
- Adults (≥18 years) with at least one prior antiretroviral regimen and HIV RNA ≤50 copies/mL during the previous 12 months were included in this analysis

Complex Regimen Definition Adapted From ARTISTRY-1

- Regimens containing at least 2 of the 3 core drug classes: INSTI, NNRTI, or bPI
- bPI-based regimens, including once-daily or STRs, due to potential challenges managing drug-drug interactions and metabolic adverse events
- Regimens requiring more than once-daily dosing or multi-tablet regimens (MTRs) (≥2 pills per day)

Regimens excluded from complex regimen classification included:

- Regimens representative of standard ART regimens (e.g., dolutegravir/rilpivirine and RAL + 2 NRTI regimens) were excluded as they do not necessarily reflect the level of treatment complexity targeted in this analysis
- Regimens indicated for heavily treatment-experienced individuals in Spain
- Long-acting injectable regimens

Analysis

- Demographic, clinical, and treatment characteristics were summarized descriptively (**Table 1**)

Results

Figure 1. Analysis Population Consort Diagram

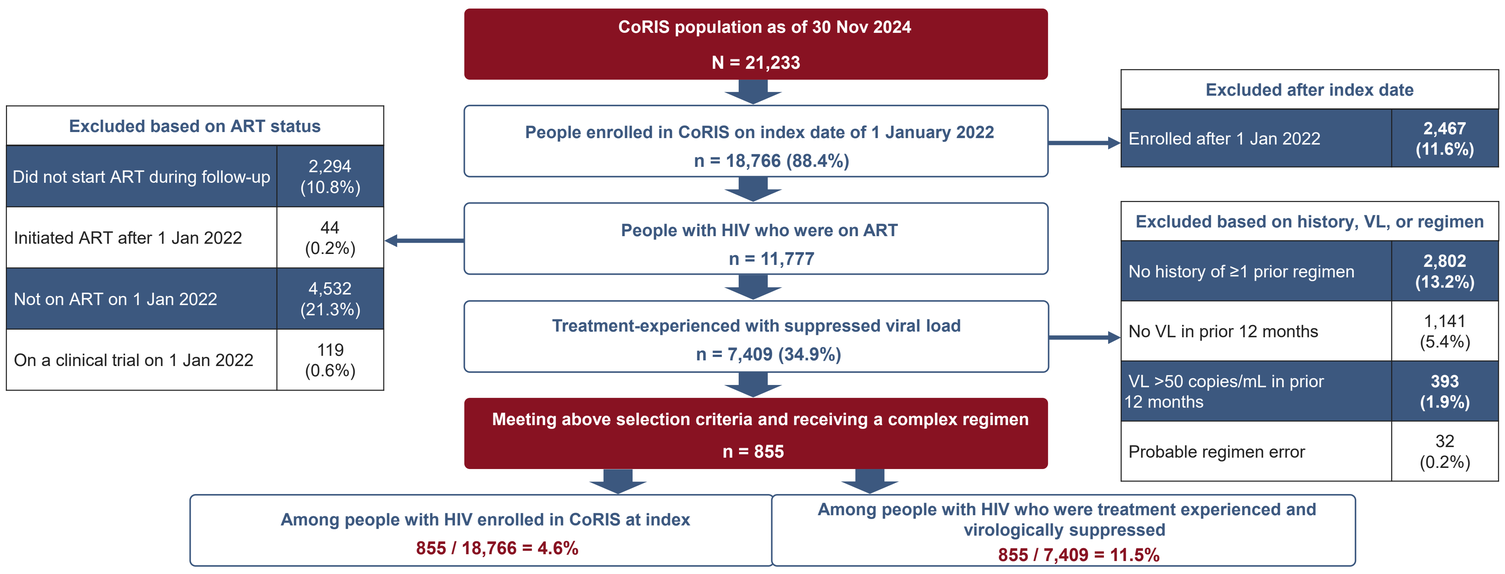


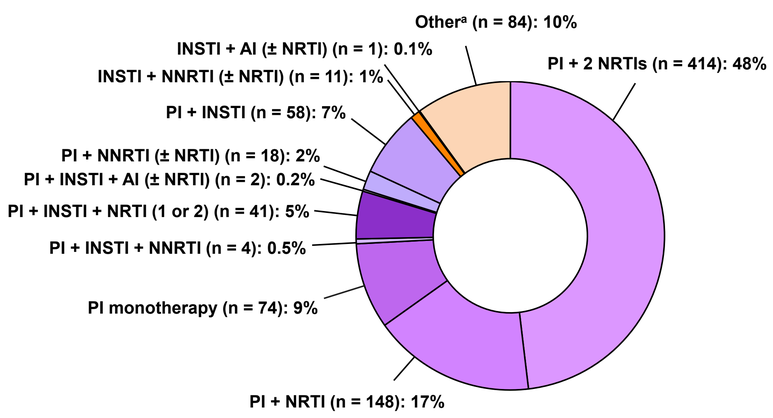
Table 1. Demographic, Clinical, and Treatment Characteristics

Characteristic	n = 855
Age ≥50 years, n (%)	358 (41.9)
Age, years, median (IQR)	47.4 (40.1–55.2)
Female sex, n (%)	167 (19.5)
Born in Spain, n (%)	482 (56.4)
Born outside Spain, n (%)	365 (42.7)
Country of birth unknown, n (%)	8 (0.9)
Time from HIV diagnosis to index, months, median (IQR)	134.7 (87.8–177.6)
CD4 count at index, cells/mm³, median (IQR)	665.0 (505.0–901.0)
Duration of HIV RNA <50 copies/mL, months, median (IQR)	57.6 (25.6–103.9)
Prior lines of antiretroviral therapy, median (IQR)	2.0 (2.0–4.0)
Time from HIV diagnosis to complex regimen initiation, months, median (IQR)	83.2 (42.3–125.6)
Current complex regimen duration, months, median (IQR)	41.3 (26.3–59.5)
Prior complex regimens, median (IQR)	2.0 (1.0–3.0)
Current regimen dosed once daily, n (%)	737 (86.2)
Current regimen dosed twice daily, n (%)	118 (13.8)
Single-tablet regimen, n (%)	397 (46.4)
Multi-tablet regimen, n (%)	458 (53.6)
No. of antiretrovirals in complex regimen, median (IQR)	4.0 (3.0–4.0)

Key Population Characteristics

- Overall, 855 participants were receiving a complex regimen, representing 4.6% (855/18,766) of the overall cohort at index and 11.5% (855/7,409) of treatment-experienced, virologically suppressed participants (**Figure 1**)
- Participants were primarily male at birth (n=688, 81%) and born in Spain (n=482, 56%) with a median age of 47.4 years (IQR: 40.1–55.2) (**Table 1**)
- Median duration of virologic suppression was 57.6 months (IQR: 25.6–103.9) and CD4 count was 665 cells/mm³ at index
- Participants had received a median of 2 prior complex regimens before index (range: 1-13) and 21% (n=179) had no prior exposure to a complex regimen
- The median number of antiretrovirals in complex regimens was 4 (IQR: 3.0–4.0) and 9.4% (n=80) had 2 antiretrovirals in their complex regimen
- Most complex regimens were bPI-based: bPI + 2 NRTIs (n = 414, 48%), bPI + NRTI dual therapy (n = 148, 17%), and bPI monotherapy (n = 74, 9%) (**Figure 2**)
- Darunavir/cobicistat/emtricitabine/tenofovir alafenamide was the most common regimen (n=332, 39%) with darunavir being the most prescribed bPI (n=746, 87%)

Figure 2. Distribution of Complex Regimens Among People With HIV Who Were Virologically Suppressed and Treatment Experienced in CoRIS (n = 855)



[a]Other: 2NRTI+NVP (n = 72; 8%), 2NRTI+ETR (n = 10; 1%), DRV/c+MVC (n = 1; 0.1%), DRV/c+MVC+RPV (n = 1; 0.1%).
AI, attachment inhibitor; INSTI, integrase strand-transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitor.

Limitations

Generalizability

- CoRIS participants are recruited exclusively from Spanish HIV clinics; results may therefore not be fully applicable to populations outside of Spain
- Since CoRIS participants were all treatment-naïve at enrollment, treatment-experienced adults with HIV who have migrated to Spain are not included; consequently, the proportion of individuals on complex regimens in CoRIS could be underestimating the true proportion in Spain

Clinical Background Information Completeness

- Resistance data not available
- Reason for being on a complex regimen not available
- Dosing information was not captured in our data source and was therefore inferred, potentially resulting in misclassification of complex regimens
- Requirement for available viral load measurements to ascertain virologic suppression may have excluded otherwise eligible participants, potentially leading to underestimation of the prevalence of complex regimens among virologically suppressed individuals

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Acknowledgments: We thank all study participants, investigators, and staff. This study was sponsored by Gilead Sciences, Inc. Editing and production assistance were provided by Aspire Scientific Ltd (UK), and were funded by Gilead Sciences, Inc.

Disclosures: AC, **HA**, **IJ**, **JIB**, **MR (Marta Rava)**, **MR (Melchor Riera)**, **RBS**, and **SMG** report research funding, consulting fees, honoraria, speaker fees, advisory board fees, and/or travel support from one or more of the following: Gilead Sciences, ViiV Healthcare, MSD, Janssen, Fundación SEIMC-GESIDA, ESCMID, Universidad Complutense de Madrid. **JNC**, **JLMB**, **NPM**, and **AM** are employees of, and own stocks/shares in, Gilead Sciences.

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HIV Glasgow; November 8–11, 2026; Glasgow, UK