SOUS L'ÉGIDE DE VIH ACTU

ÉDITÉ PAR KEPHREN PUBLISHING

AVEC LE SOUTIEN DE GILEAD

Soirée inédite

Les Francophones de Glasgow

MARDI 12 NOVEMBRE 2024

à partir de 18h00

CROWNE PLAZA GLASGOW

Congress Road - GLASGOW, G3 8QT, UK

En direct du HIV GLASGOW pour décrypter et mettre en perspective les actualités clés dans le VIH

Focus sur les études françaises

>>>

Partage et discussions entre francophones

>>>

Top 3 des incontournables du HIV Glasgow 2024

COMITÉ SCIENTIFIQUE

MODÉRATEUR
Jade GHOSN
Hôpital Bichat, Paris

RAPPORTEUR
Matteo VASSALLO
CH Cannes

RAPPORTEUR
Fabrice BONNET
CHU Bordeaux

RAPPORTEUR
Anne-Geneviève MARCELIN
Pitié-Salpêtrière, Paris

Liens d’intérêt

Fabrice BONNET	ViiV, Gilead, MSD
Jade GHOSN	ViiV, Gilead
Anne-Geneviève MARCELIN	ViiV, Gilead, MSD
Matteo VASSALLO	ViiV, Gilead, MSD

Resistance aux traitements

Anne-Geneviève MARCELIN, Paris

No impact of the M184I/V mutation on the efficacy of tenofovir or abacavir+lamivudine+doravirine in HIV treatment-experienced people

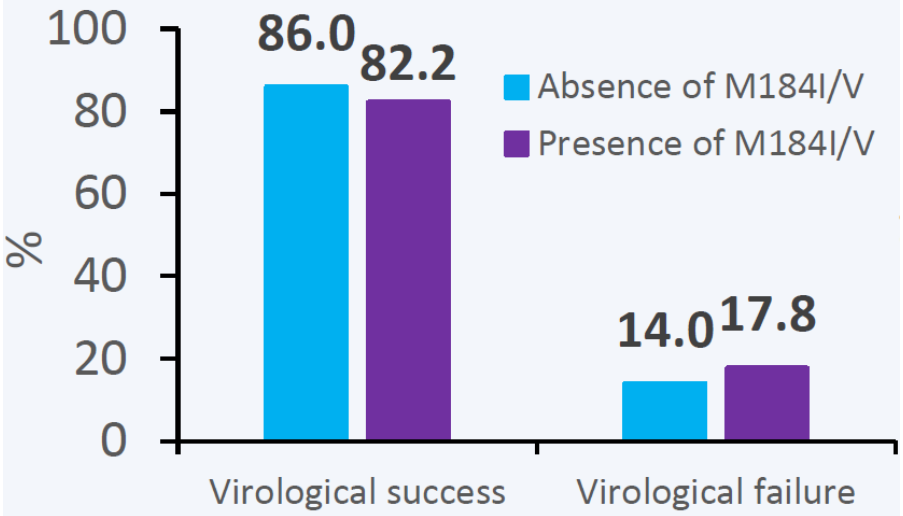
C Soulié[1], A Baldé[2], D Fofana[3], C Charpentier[4], P Bonnafous[1], J Sourice[5], A De Monte[6], V Avettand-Fenoel[7], H Le Guillou-Guillemette[8], L Bocket[9], S Raymond[10], M-A Trabaud[11], B Montes[12], A Maillard[13], C Hartard[14], E Alessandri-Gradt[15], E Brochot[16], A Signori-Schmuck[17], L Assoumou[2], **A-G Marcelin[1]**

1 Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, AP-HP, Hôpitaux Universitaires Pitié Salpêtrière - Charles Foix, laboratoire de virologie, Paris, France; 2 Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, Paris, France; 3 Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, AP-HP, Hôpital Universitaire Saint Antoine, laboratoire de virologie, Paris, France; 4 Université Paris Cité, INSERM UMR 1137 IAME, AP-HP Nord Hôpital Bichat–Claude-Bernard, Laboratoire de Virologie, Paris, France; 5 Laboratoire de Virologie, CHU Nantes, Nantes, France; 6 Laboratoire de Virologie, CHU Nice, Nice, France; 7 Hôpital Necker, APHP GHU Centre - Université Paris Cité, Laboratoire de Virologie, Paris, France; 8 Laboratoire de Virologie, CHU Angers and HIFIH Laboratory EA 3859, LUNAM, Angers, France ; 9 Univ. Lille, CHU Lille, Laboratoire de Virologie, Lille, France; 10 INSERM UMR 1291, Laboratoire de Virologie, CHU Toulouse Purpan, Toulouse, France; 11 Laboratoire de Virologie, Institut des Agents Infectieux, Hospices civils de Lyon, Centre de Biologie Nord, Hôpital de la Croix Rousse, Lyon, France; 12 Laboratoire de Virologie, CHU Montpellier, Univ Montpellier, Montpellier, France ; 13 Laboratoire de Virologie, CHU de Rennes, Rennes, France; 14 CHRU Nancy, Laboratoire de Virologie, Nancy, France; 15 CHU de Rouen, Université de Rouen Normandie UNIRouen, Rouen, France; 16 CHU Amiens, Faculté de pharmacie Amiens, Amiens, France; 17 CHU Grenoble-Alpes, Laboratoire de Virologie, Grenoble, France.

CONCLUSIONS

- In antiretroviral experienced PLWHIV switching to DOR+ 3 TC ABC or TDF in clinical practice, we found no evidence of an impact of the previously acquired M 184 I/V mutation on treatment response
- A higher zenith of HIV RNA VL was the only factor associated with the VF as it has been previously shown in the analysis of the entire cohort of PLWHIV receiving a regimen including DOR or in different contexts of
- ARV regimen switching 1 4
- Limitation only a small proportion of the PLWHIV were treated by DOR+ 3 TC+ABC, so the results for this combination should be taken cautiously
- These results should be confirmed in prospective clinical trials

Proportion of Virological Failure and Blips



Kinetics of non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance-associated mutations in HIV-1 blood reservoir in NNRTI-experienced people with HIV: the KINNDeR study

P123

Thomas Drumel[1], Justine Source[1], Audrey Rodallec[1], Clotilde Allavena[2], Colin Deschanvres[2], Berthe-Marie Imbert-Marcille[1], François Raffi[2], Elisabeth André Garnier[1]

1 : Nantes Université, CHU Nantes, Service de Virologie, F-44000, Nantes, France ,
2 : Nantes Université, CHU Nantes, Service de maladies infectieuses et tropicales, F-44000, Nantes, France

Email contact : thomas.drumel@chu-nantes.fr

Introduction

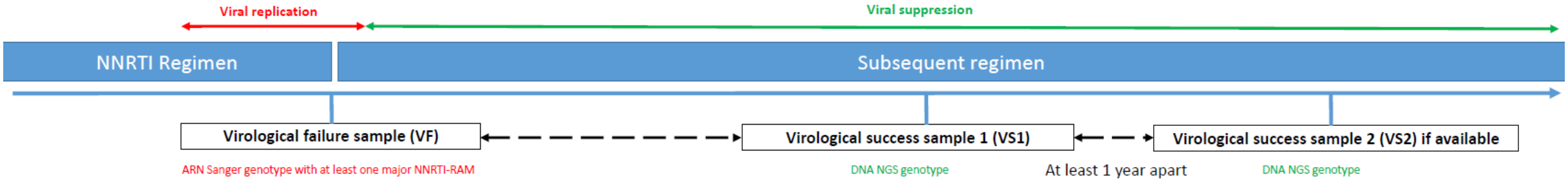
- **Objective :** to describe the temporal evolution of archived resistance-associated mutations (RAM) to non-nucleoside reverse transcriptase inhibitor (NNRTI) using Next Generation Sequencing (NGS)

Patients Characteristics at VS1 (n=79)

	Median	IQR
Age (years)	58	55-62
Zenith plasma HIV-1 RNA (log_{10} c/ml)	5.4	4.7-5.8
CD4 nadir (/mm^3)	127	35-225
Duration of replication on NNRTI (days)	310	120-1088
Time between HIV diagnosis and VS1, (years)	26	21-30
Time between VF and VS1 (years)	16	11-18
Time between VS1 and VS2 (years)	3	2-5
Duration of viral suppression before VS1 (years)	10	5-13
HIV-1 DNA at VS1 (log_{10} c/10^6 cells) (n=79)*	2.8	2.5-3
HIV-1 DNA at VS2 (log_{10} c/10^6 cells) (n=62)*	2.7	2.4-2.9
Zenith viral load at VF**	4.2	3.6-4.9

* p=0.0006 DNA viral load decreased significantly between VS1 and VS2
**NNRTI at VF : Nevirapine (n=51) Efavirenz (n=27) and Etravirine (n=1)

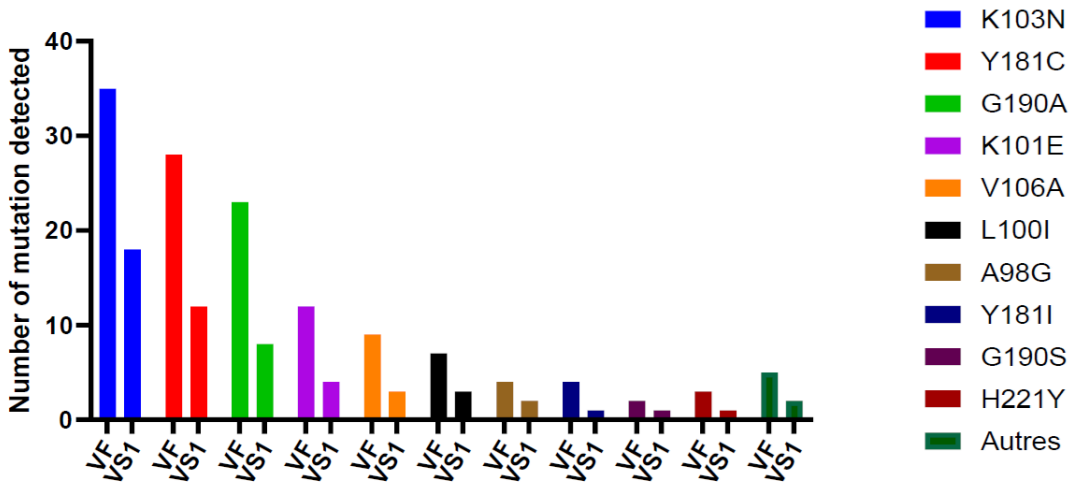
SAMPLES AND STUDY DESIGN



D'après le poster de Drumel et al. Kinetics of non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance-associated mutations in HIV-1 blood reservoir in NNRTI-experienced people with HIV: the KINNDeR study. P123. HIV Glasgow 2024

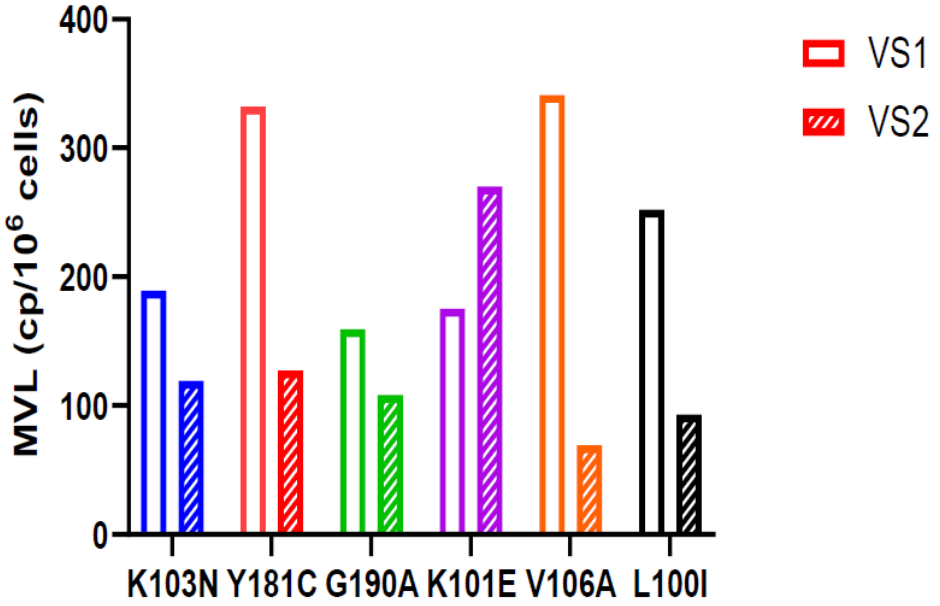
Results

NNRTI RAM detected at VF (RNA Sanger) and at VS1 (DNA NGS)

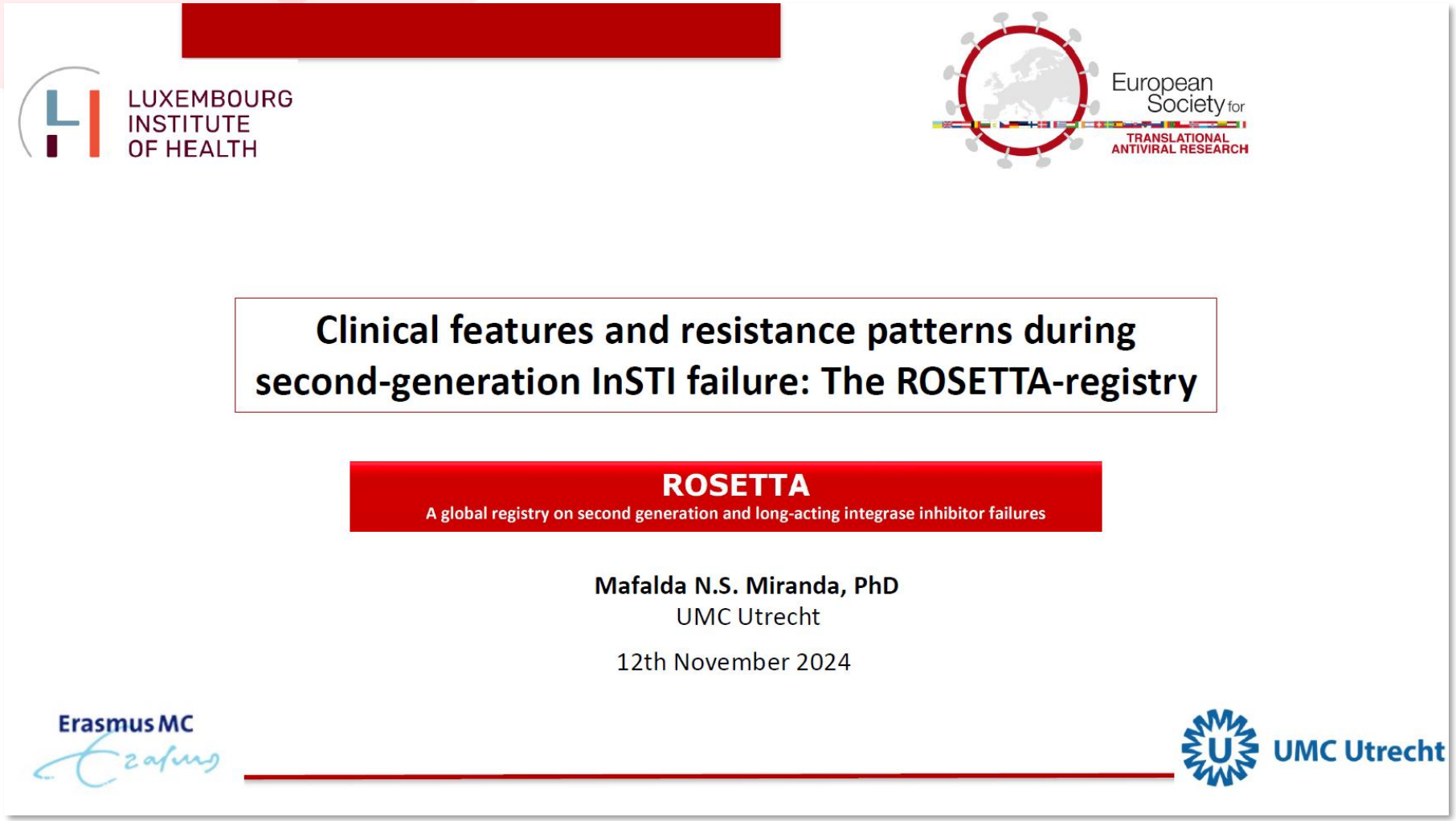


The frequency of detection of the mutations between Sanger sequencing at VF and NGS sequencing at VS1 decreased at the same rate for every mutation

Change in DNA mutational viral load between VS1 and VS2 for the 6 most frequent mutations detected at VS1



D'après le poster de Drumel et al. Kinetics of non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance-associated mutations in HIV-1 blood reservoir in NNRTI-experienced people with HIV: the KINNDeR study. P123. HIV Glasgow 2024



D'après la communication orale de Miranda et al . Clinical features and resistance patterns during second-generation INSTI failure: the ROSETTA-registry. O31. HIV Glasgow 2024

A case registry that systematically collects otherwise scattered clinical, genotypic and phenotypic data

Inclusion criteria

- On ART for at least 6 months without evidence of current interruption
- Virological failure on 2nd-gen InSTI based ART in Europe, Africa or America*
- Record of current ART and previous InSTI exposure
- Integrase (IN) sequences or samples drawn at time of failure to perform resistance testing (by the ROSETTA coordination team)

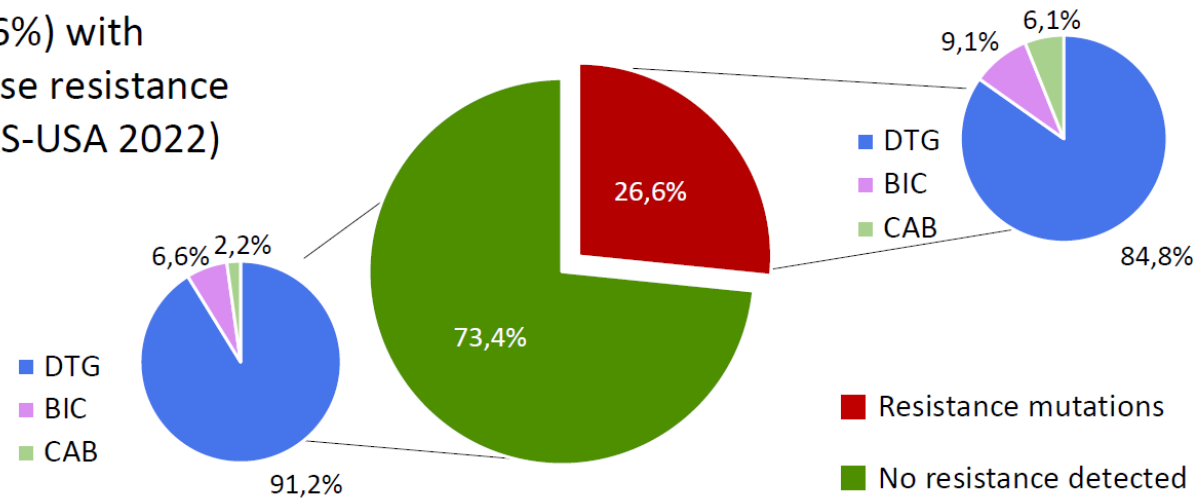
*Virological failure: 2 consecutive viral loads > 50 copies/mL in plasma or single VL > 200 copies/mL in plasma orsingle VL of >50 copies/mL in CSF
D'après la communication orale de Miranda et al . Clinical features and resistance patterns during second-generation INSTI failure: the ROSETTA-registry. O31. HIV Glasgow 2024

Prevalence of resistance to 2nd-gen InSTI in database

- **125 cases**

Median Age at time of failure	41 years	IQR (34 -51 years)
Median duration on ART at time of failure of 2nd-gen InSTI based ART	**23 months**	IQR: 7-91 months

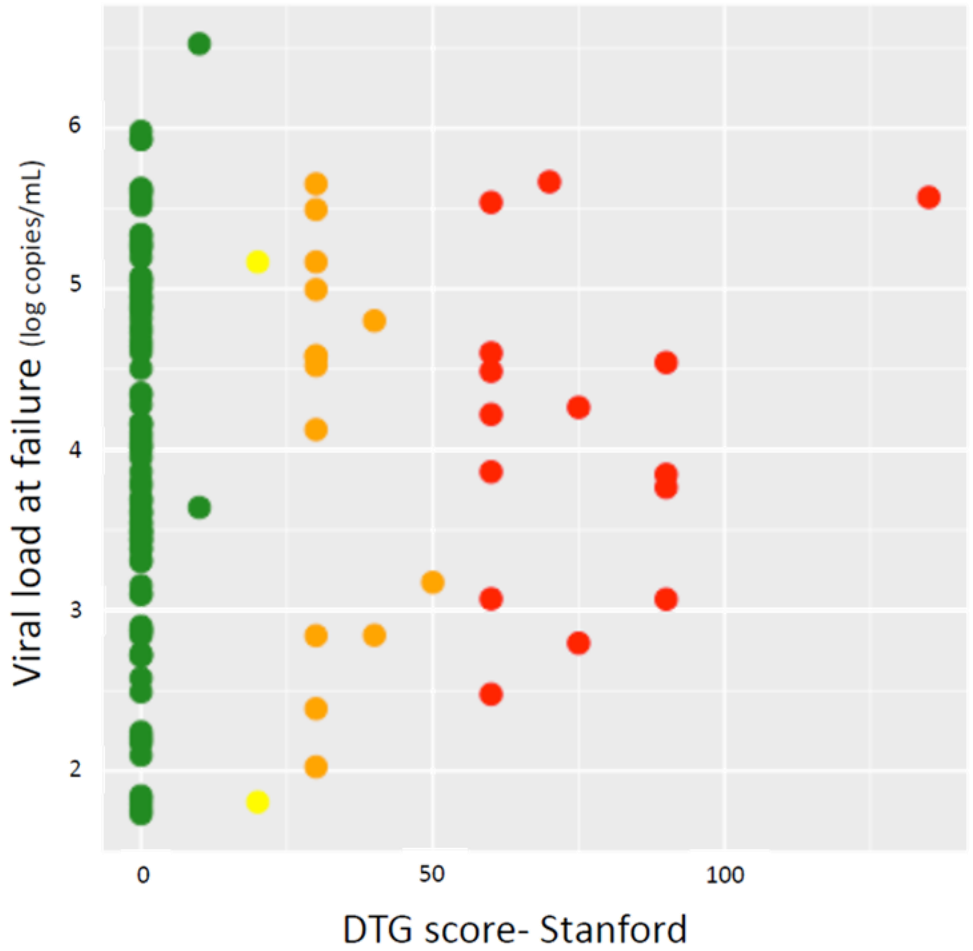
33 cases (26.6%) with major integrase resistance mutations (IAS-USA 2022)



	Resistance	No Resistance	p-value
Duration on 2nd-gen InSTI	13 months (median) IQR: 6-26	8 months (median) IQR: 4-16	<0.001

D'après la communication orale de Miranda et al . Clinical features and resistance patterns during second-generation INSTI failure: the ROSETTA-registry. O31. HIV Glasgow 2024

DGT eresistance score related to viral load at time of failure



Predicted level of resistance

- High level: Score >= 60
- Intermediate level: Score 30 to <60
- Low level: Score 15 to <30
- Susceptible/Potential low level: Score <10 to <15

N=111 cases with DTG-based ART

D'après la communication orale de Miranda et al . Clinical features and resistance patterns during second-generation INSTI failure: the ROSETTA-registry. O31. HIV Glasgow 2024

Different pathways of resistance based on previous exposure to 1st-gen InSTI

Pre-exposure to 1st-gen InSTI

Subtype	Current InSTI	IAS-USA InSTI resistance mutations at failure
A1	DTG	155H
A6	DTG	140A, 148R
B	BIC	97A, 147G, 155H
B	CAB	140S, 148K
		97A, 138K, 140S, 148H
B	DTG	97A, 140S, 148H
		138A, 140S, 148H
		138K, 140A, 147G, 148R, 155H
D	DTG	97A, 140S, 148H
F1	DTG	L74M, 97A, 138K, 143R, 147G
02_AG	DTG	97A, 147G, 155H
95_02B	DTG	92Q, 138K, 147G, 155H

118R and 263K are only observed in those who have not been pre-treated with 1st-gen InSTI

No pre-exposure to 1st-gen InSTI

Subtype	Current InSTI	IAS-USA InSTI resistance mutations at failure
A1	DTG	**263K**
		263K
A6	DTG	138K, 147G
B	BIC	L74M, 138A, 140A, 148R
		97A, 138T, 140S, 148H
B	DTG	**263K**
		263K
		138K, 147G, 155H
		92Q, 138A, 147G, 155H
C	DTG	**118R**
		263K
		263K
		155H, **263K**
D	DTG	66I, 74LM, **118R**, 138K
F1	DTG	**263K**
G	DTG	**263K**
		263K
		74LM, **118R**
02_AG	DTG	66I, 74M, **118R**, 138K, 153Y
		138A, 147G, 155H
31_BC	DTG	**263K**

D'après la communication orale de Miranda et al . Clinical features and resistance patterns during second-generation INSTI failure: the ROSETTA-registry. O31. HIV Glasgow 2024

Virological Outcomes and Associated Factors Among Treatment-Naive Patients With HIV-1 on Dolutegravir based regimen in a Programmatic Setting in Thailand

Napon Hiranburana[1], Opass Putcharoen[2], Cheewanan Lertpiriyasuwat[3], Sairat. Noknoy[3], Jiratchaya Sophonphan[1], Supunnee Jirajariyavej[4], Stephen J. Kerr[1,5,6] Ploenchan Chetchotisakd[7], Chureeratana Bowonwatanuwong[8], Kiat Ruxrungtham[1], Anchalee Avihingsanon[1,9]

[1]HIV-NAT, Thai Red Cross AIDS Research Center, Bangkok, Thailand,
[2]Faculty Medicine, Chulalongkorn University, Medicine, Bangkok, Thailand,
[3]Division of AIDS and STI, Department of Disease Control, Ministry of Public Health, Nonthaburi, Thailand,
[4]Taksin Hospital, Bangkok, Thailand,
[5]Biostatistics Excellence Centre, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand,
[6]The Kirby Institute, University of New South Wales, SydneyA, Australia,
[7]Faculty of Medicine, Srinagarind Hospital, Khon Kaen University, Khon Kaen, Thailand,
[8]Thai AIDS Society, Bangkok, Thailand,
[9]Center of Excellence in Tuberculosis, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand

D’après la communication orale de Hiranburana et al. Virological outcomes and associated factors among treatment-naive patients with HIV1 on dolutegravir based regimen in a programmatic setting in Thailand. O32. HIV Glasgow 2024

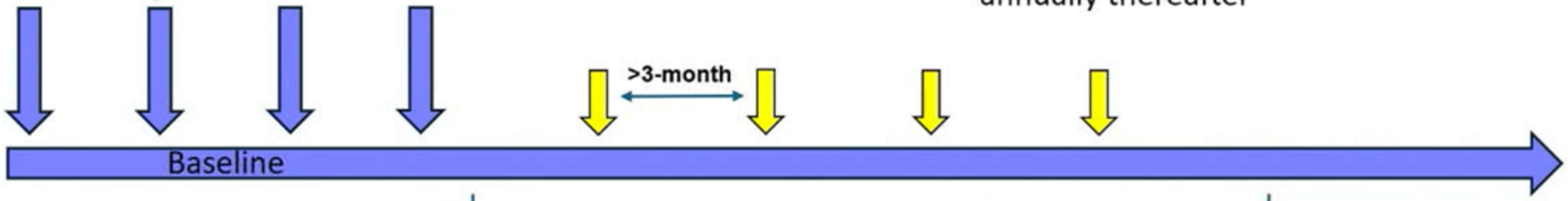
Study flow

Grouping

1) Same day
2) Rapid (2-7days)
3) 8 days-1 month
4) >1month

Outcome

- **Viral suppression** : VL **< 50** copies/mL, **< 200** copies/mL and **< 1000** copies/mL
- **Virologic failure (VF):** VL **≥ 1000** copies/mL after ART initiation at least six months and annually thereafter



Diagnosed HIV

- PLWH aged ≥15 years
- Initiated DTG as a 1st line ART between 2020 and 2023
- At least 1 recorded VL after started ARV (≥ 6 months)

Viral load outcomes are reported for the following time points: Post-TLD VL (VL measurement closest to 6, 12, 24 and 36 months). we used a 3-month window around each time point

***Lost to follow-up (LTFU) was defined as not attending clinic visits for ≥ 12 months, irrespective of whether patients later returned to program after ART initiation.**

D'après la communication orale de Hiranburana et al. Virological outcomes and associated factors among treatment-naive patients with HIV1 on dolutegravir based regimen in a programmatic setting in Thailand. O32. HIV Glasgow 2024

Primary outcome

- The proportion of VL **< 50 copies/mL**, VL **< 200 copies/mL** and Virologic failure (VL **≥ 1 000 copies/mL**) at last visit

Secondary outcome

- **Factors associated with Virologic failure**
- Comparing virologic failure rates between **timing of ART** initiation:
  Same day, Rapid (2-7 days), 8 days-1 month, and delayed > 1 month

D'après la communication orale de Hiranburana et al. Virological outcomes and associated factors among treatment-naive patients with HIV1 on dolutegravir based regimen in a programmatic setting in Thailand. O32. HIV Glasgow 2024

Virological treatment outcomes

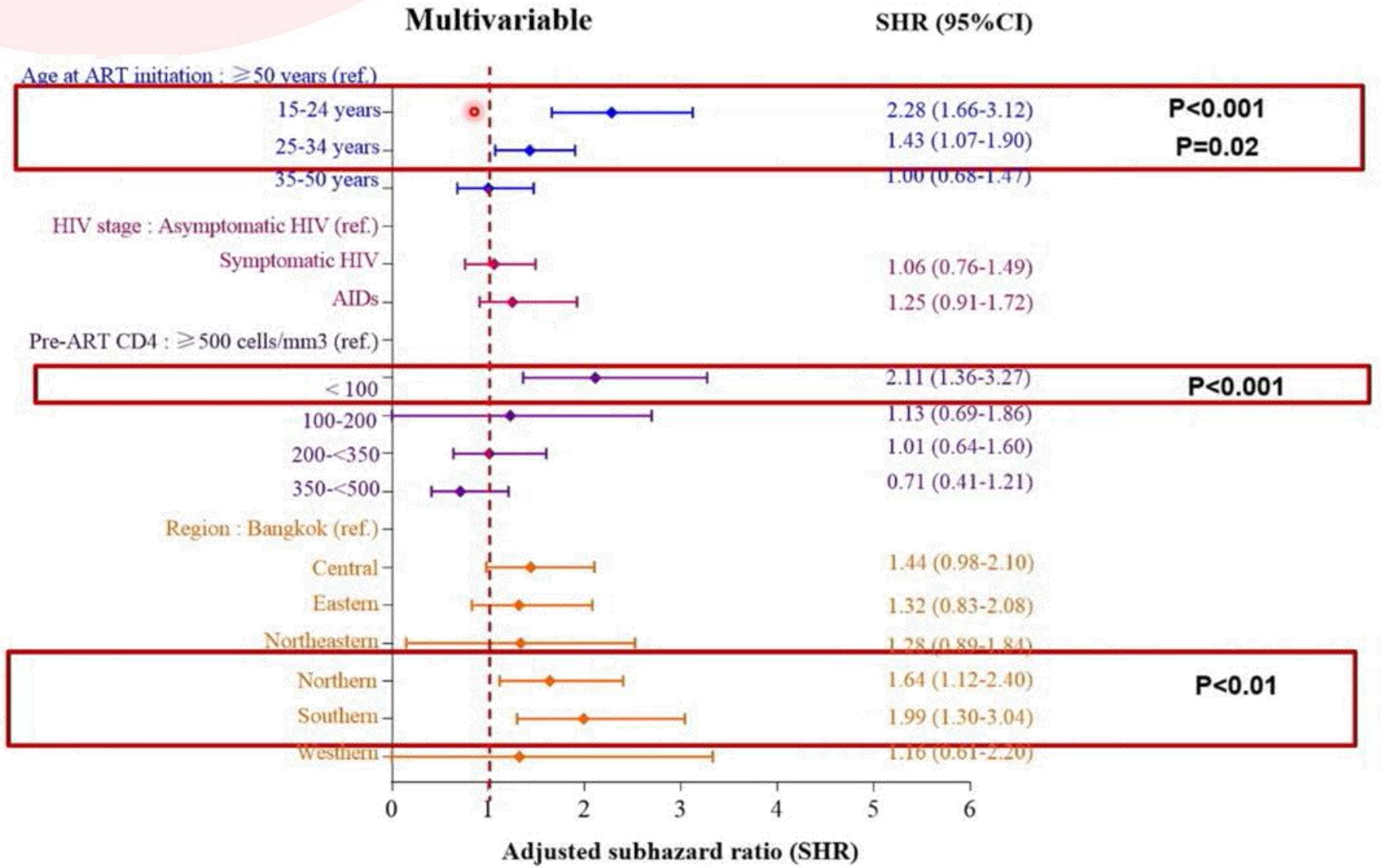
- **Median follow-up time of 8.7 (IQR: 6.8-12.4) months,**

	VL < 50 cps/mL	VL < 200 cps/mL	VL < 1,000 cps/mL
Total (N=10,475)	8854 **(84.5%)**	9982 (95.3%)	10146 **(96.9%)**
ART initiation			
- **Same-day (N=2,766)**	2373 (85.8%)	2653 (95.9%)	2693 (97%)
- **2-7 days (N=1,395)**	1170 (83.9%)	1340 (96.1%)	1363 (97.7%)
- **8-29 days (N=2,770)**	2314 (83.5%)	2642 (95.4%)	2684 (96.9%)
- **≥ 30 days (N=3,544)**	2997 (84.6%)	3347 (94.4%)	3416 (96.4%)

Table: Proportion of virological suppression at last visit after DTG-based ART initiation for all patients

D'après la communication orale de Hiranburana et al. Virological outcomes and associated factors among treatment-naive patients with HIV1 on dolutegravir based regimen in a programmatic setting in Thailand. O32. HIV Glasgow 2024

Forest plot of factors associated with virological failure after DTG initiation



D'après la communication orale de Hiranburana et al. Virological outcomes and associated factors among treatment-naive patients with HIV1 on dolutegravir based regimen in a programmatic setting in Thailand. O32. HIV Glasgow 2024

Médicaments à libération prolongée

Matteo VASSALLO, Cannes

Update on long-acting treatment in virally suppressed people

Professor Chloe Orkin

Dean for Healthcare Transformation

Director SHARE Collaborative for Health Equity

Queen Mary University of London and Barts Health NHS Trust

SHARE
RESEARCH FOR HEALTH EQUITY

D’après la communication orale d’Orkin et al. Update on long-acting treatment for virally suppressed people. HIV Glasgow 2024

2-monthly CAB+RPV

High efficacy with low rates of confirmed virological failure (CVF)

	ATLAS 2M	CARISEL (Protocol 213189)	SOLAR (Protocol 213500)	CARES
	n=522 (ITT-E)[1,2]	n=430 (ITT-E)[3]	n=447 (mITT-E)[4]	n=255 (ITT-E)[5]
Virologically suppressed (VL <50 c/mL)	**94%** at Week 48*	**87%** at Month 12†	**90%** at Month 12‡	**96%** at Week 48§
CVF	**1.7%** (n=9) by Week 48*	**0.2%** (n=1) by Month 12†	**0.7%** (n=3) by Month 12‡	**0.8%** (n=2) by Week 48§

- **Arm-E,** enhanced arm; **Arm-S,** standard arm; **CVF,** confirmed virologic failure; **ITT-E,** intention-to-treat exposed; **mITT-E,** modified ITT-E; **SVF,** suspected virologic failure; **SWI,** start with injection

1. Overton ET, et al. Lancet. 2021;396:1994–2005; **2.** Overton ET, et al. Clin Infect Dis. 2023;76:1646–54 (and suppl. appendix); **3.** Jonssen-Oldenbüttel C, et al. JAIDS. 2024:10.1097/QAI.0000000000003448
4. Ramgopal MN, et al. Lancet HIV. 2023;10:e566–77; **5.** Kityo C, et al. Lancet Infect Dis. 2024:S1473-3099(24)00289-5.

D'après la communication orale d'Orkin et al. Update on long-acting treatment for virally suppressed people. HIV Glasgow 2024

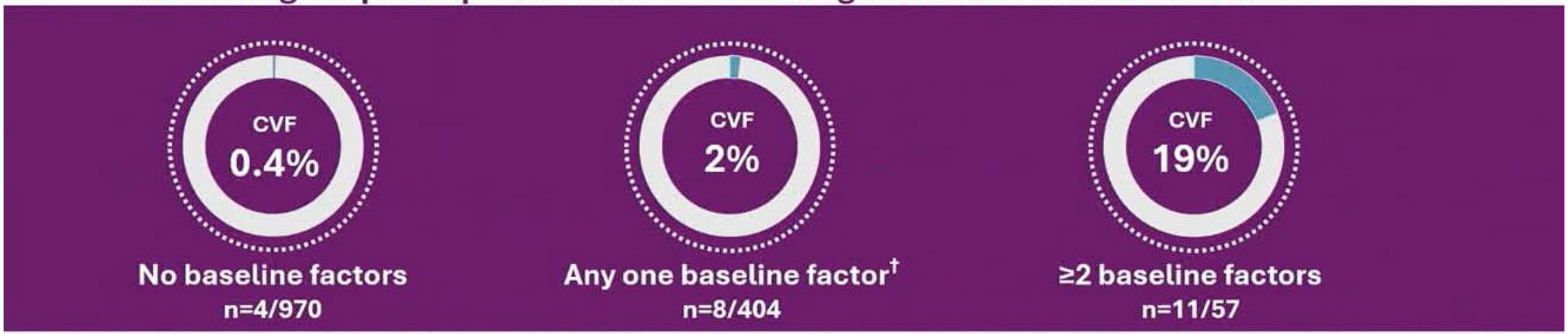
Multivariable analysis: baseline risk factors for CVF

Archived RPV mutations

HIV-subtype A6

BMI ≥30 kg/m²

Percentage of participants with CVF according to number of baseline factors



† Driven primarily by archived RPV RAMs and HIV-1 subtype A6

CVF occurred in 0.5% with high BMI ≥30 kg/m²

- *CVFs identified by Week 48 for ATLAS, Week 124 for FLAIR, and Week 152 for ATLAS-2M

NOTE: Prevalence of ≥2 baseline factors in Phase III study participants was low (4.0%) ;3.8% (n=6/157) of those with HIV-1 subtype A6/A1 only, and 3.2% (n=1/31) of those archived RPV RAMs only

BMI, body mass index; **CVF**, confirmed virologic failure; **RAM**, resistance-associated mutation

Orkin C, et al. CID 2023

D'après la communication orale d'Orkin et al. Update on long-acting treatment for virally suppressed people. HIV Glasgow 2024

HIV DRUG THERAPY GLASGOW 2024

Long-acting treatment for non-virally suppressed individuals: real world evidence

Monica Gandhi MD, MPH
Medical Director, Ward 86 HIV Clinic and Director, Center for AIDS Research
Division of HIV, Infectious Diseases, and Global Medicine, UCSF
November 11, 2024

D’après la communication orale de Gandhi et al. Long-acting treatment for non-virally suppressed individuals on cabotegravir + rilpivirine: real world evidence. HIV Glasgow 2024

Is HIV epidemic control by 2030 realistic?

Chris Beyrer, Georgia D Tomaras, Huub C Gelderblom, Glenda E Gray, Holly E Janes, Linda-Gail Bekker, Gregorio Millett, Giuseppe Pan
Susan Buchbinder, Lawrence Corey

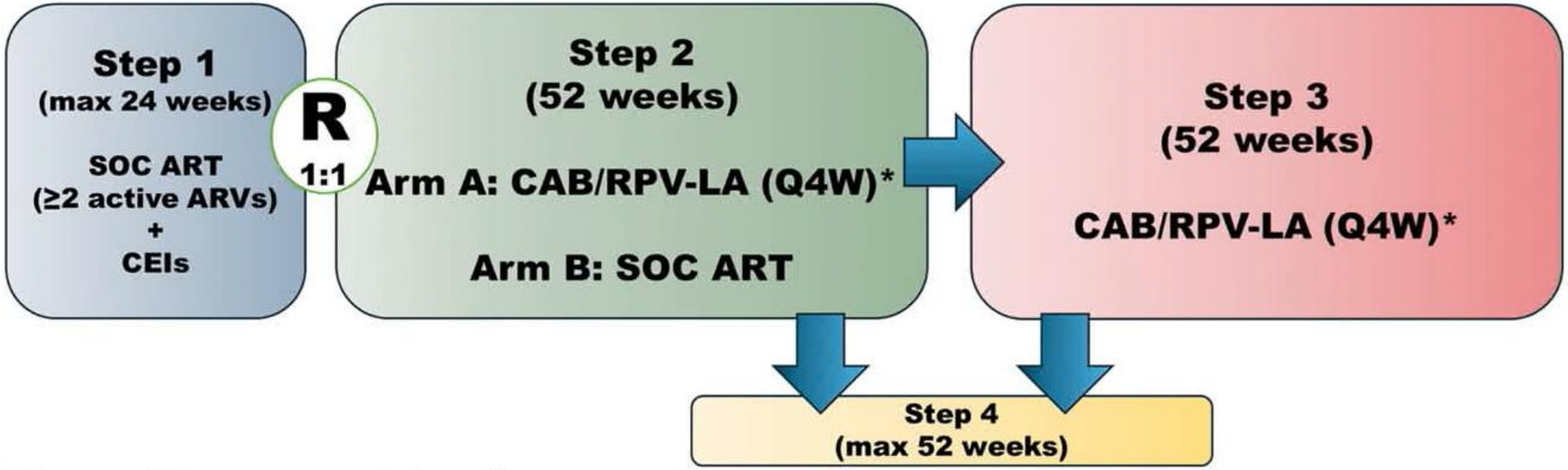
THE LANCET HIV

UNAIDS update 2024 (AIDS at a Crossroads):

- 39.9 million people with HIV (highest) not counting Russia so probably >40 million
- 1.3 million new infections last year unchanged from 2022 update
- 630K deaths last year unchanged from 2022 update
- 43.3 million deaths total from beginning of epidemic and 88.4 infections
- Only 77% on ART (72% suppressed)
- Stigma, rise of anti-LGBTQ sentiment, 8% loss of funding from 2020-23 playing roles

D'après la communication orale de Gandhi et al. Long-acting treatment for non-virally suppressed individuals on cabotegravir + rilpivirine: real world evidence. HIV Glasgow 2024

Data in those with adherence challences: A5359 Study design



CEIs= conditional economic incentives
***Optional Oral lead-in**

Primary Outcome: Regimen failure defined as the earliest occurrence of confirmed virologic failure or treatment discontinuation in Step 2

LATITUDE

ACTG

D'après la communication orale de Gandhi et al. Long-acting treatment for non-virally suppressed individuals on cabotegravir + rilpivirine: real world evidence. HIV Glasgow 2024

ACTG A5359 LATITUDE: Baseline Characteristics

Characteristic	Step 1 Total (N = 434)
Median age, yr (Q1, Q3)	40 (32, 51)
▪ ≤30, n (%)	88 (20)
▪ 31-50, n (%)	232 (53)
▪ ≥51, n (%)	114 (26)
Female at birth, n (%)	129 (30)
Transgender spectrum, n (%)	21 (5)
Race, n (%)	
▪ Black	277 (64)
▪ White	117 (27)
▪ Other/multiple/unknown	40 (9)
Hispanic or Latino/a, n (%)	75 (17)
Current or previous injection drug use, n (%)	61 (14)
Nonadherence criteria, n (%)	
▪ Lost to f/u	87 (20)
▪ Poor response	283 (65)
▪ Both	64 (15)
Median time since HIV diagnosis, yr (Q1, Q3)	13 (7, 21)

Step 2

Characteristic	LA CAB + RPV (n = 146)	SoC (n = 148)
BL HIV-1 RNA >200 c/mL, n (%)	24* (17)	10 (7)
Median BL CD4 count, cells/mm^3 (Q1, Q3)	417 (198, 688)	374 (198, 605)

*Includes 8 participants with HIV-1 RNA >10,000 c/mL.

- **80% Government funded program**
- 3% Self-pay
- 7% Private
- 10% Other

- 61% In own house/apt
- 14% Parents' house
- 13% Someone Else's House
- **10% Unstable/Homeless***

*Shelter/Welfare hotel, Halfway/Boarding House On the Street, Residential Treatment Facility

Rana. CROI 2024. Abstr 212.

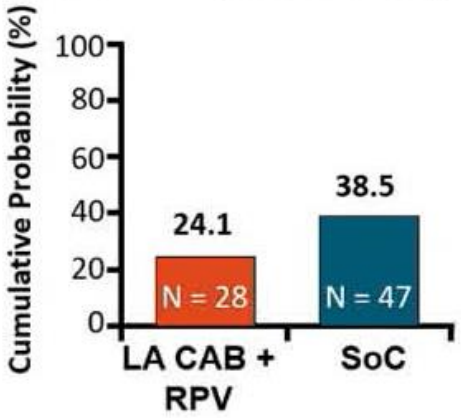
Courtesy of CCO

ACTG A5359 LATITUDE: Efficacy Outcomes

Primary Outcome

Regimen Failure

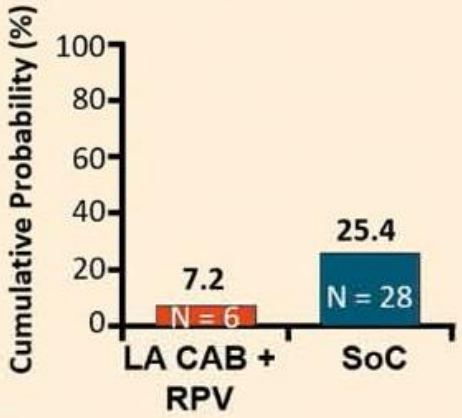
Difference -14.5%
Nominal 98.75% CI (-29.8% to 0.8%)



Secondary Outcomes

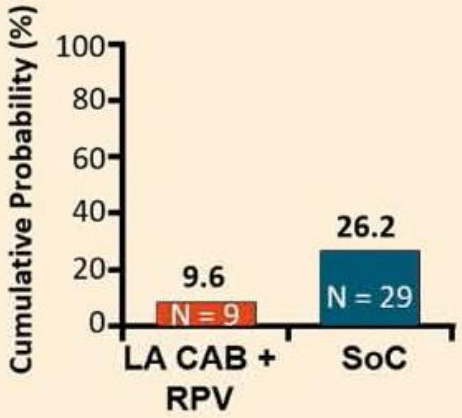
Virologic Failure

Difference -18.2%
Nominal 98.75% CI (-31.1% to -5.4%)



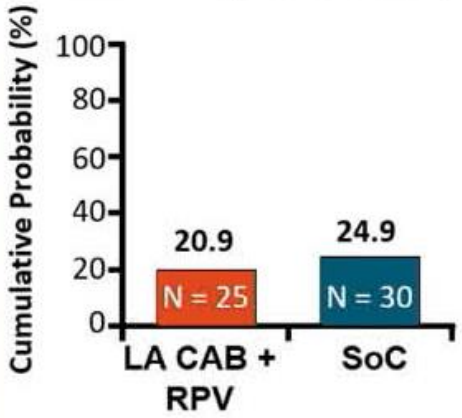
Treatment-Related Failure

Difference -16.6%
Nominal 98.75% CI (-29.9% to -3.3%)



Permanent Treatment Discontinuation

Difference -4.1%
Nominal 98.75% CI (-18.0% to 9.8%)



1 additional virologic failure after Wk 24 included in secondary endpoints, but not primary

Rana. CROI 2024. Abstr 212.

Courtesy of CCO

D'après la communication orale de Gandhi et al. Long-acting treatment for non-virally suppressed individuals on cabotegravir + rilpivirine: real world evidence. HIV Glasgow 2024

Demonstration project at Ward 86 HIV Clinic

Inclusion criteria of trials:

- Virologically suppressed x at least 16 weeks on oral regimen first
- No history of virologic failure
- Only K103N in NNRTI; no INSTI mutations
- Oral CAB/RPV x 28 days but direct-to-inject approved FDA March ‘22

Inclusion criteria of Ward 86

- Need not be virologically suppressed or take oral ART before injectables
- No RPV or INSTI mutations (strengthened criteria later)
- **Express willingness to come to clinic q4 weeks, contact information, outreach from staff**
- Rigorous protocol, Biweekly review of patients

Descriptive statistics summarized patient characteristics, median/range number of injections received, viral suppression outcomes, stratified by viral load ≥30 copies/mL at LA-ART initiation; Kaplan Meier plot for viremic

Gandhi et al. Annals of Internal Medicine July 2023

D’après la communication orale de Gandhi et al. Long-acting treatment for non-virally suppressed individuals on cabotegravir + rilpivirine: real world evidence. HIV Glasgow 2024

Results

Table 1: Demographics and clinical characteristics of cohort in Ward 86 LA ART program (n=133)

Characteristic	Distribution, n (%)
Age (median, range)	45 (38-45) years
Gender	
Cis Man	117 (88%)
Cis Woman	11 (8%)
Transgender Woman	5 (4%)
Race/ethnicity	
Black	21 (16%)
Latino/a	50 (38%)
White	43 (32%)
Multiracial	19 (14%)
Housing	
Unstable	77 (58%)
Stable	45 (34%)
Homeless	11 (8%)
Insurance	
Medicare or Medicaid or both	130 (98%)
ADAP	3 (2%)
Current stimulant use	44 (33%)
Major mental illness	51 (38%)
Virologically non-suppressed (>30 copies/ml)	57 (43%) with log10 viral load (mean, STD) 4.21 (1.30)
CD4 count (median with interquartile range)	Virologically suppressed 616 (395–818) Virologically non-suppressed 215 (75–402)

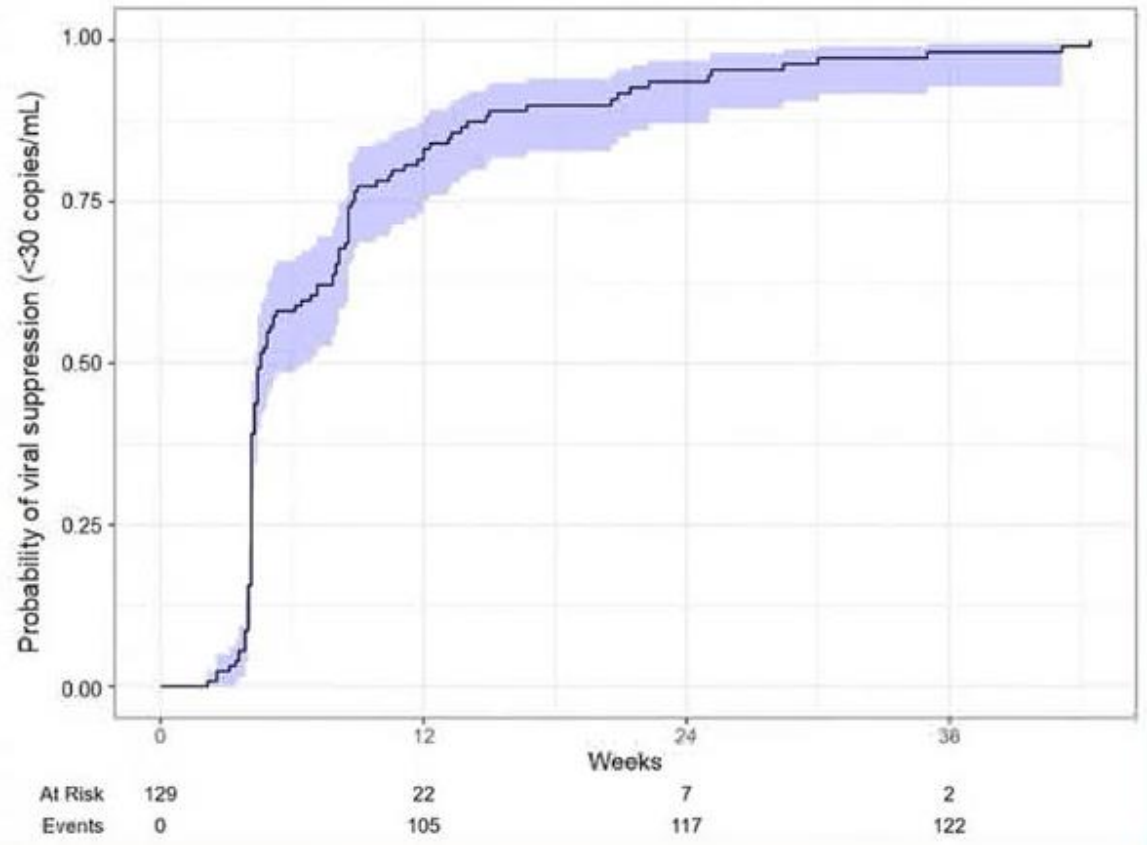
* Note: ADAP is AIDS Drug Assistance Program; Baseline CD4 defined as the CD4 count closest to and including date of first injection. Median time from CD4 count to first injection was 70 (range 0 to 882) days

- Between June 2021-November 2022, 133 PWH started on LA-ART, 76 suppressed on oral ART, 57 (43%) with viremia
- Diverse (68% non-White; 88 (66%) unstably housed; 44 (33%) endorsed substance use)
- Median CD4 count in those with viremia lower than those w/ suppression
- In those with virologic suppression, 100% (95% CI 94%-100%) remained suppressed (median 26 weeks (2-42) for whole cohort)
- Among viremic PWH, at median of 33 days, 55 suppressed, 2 had early virologic failure.
- 97.5% (89.1 to 99.9%) expected to achieve virologic suppression by median 26 weeks
-

Gandhi Annals of Internal Medicine 2023

D'après la communication orale de Gandhi et al. Long-acting treatment for non-virally suppressed individuals on cabotegravir + rilpivirine: real world evidence. HIV Glasgow 2024

Ward 86 PWH on LA-ART had rates of 48-week VS that did not differ among those starting with of without viremia



- 370 PWH on LA ART at Ward 86 as of October 2024 (129 started with viremia >50 copies/ml)
  - 40% had housing instability, 46% substance use.
- Substance use (OR 1.22), unstable housing (OR=1.11), and CD4 < 200 (1.21) higher in those with viremia than VS
- Median time to achieve VS (<=30 copies/ml) in PWH with viremia 32d
- At 48 weeks, 99.4% of those who started with VS remained suppressed and 97.9% of those with initial viremia achieved VS (not significantly different p 0.61)

Spinelli M. submitted

D'après la communication orale de Gandhi et al. Long-acting treatment for non-virally suppressed individuals on cabotegravir + rilpivirine: real world evidence. HIV Glasgow 2024

Both IAS-USA guidelines (March 1, 2024) and DHHS guidelines (September 1, 2024) updated to include the use of LA-ART in those with adherence challenges/viremia

March 1, 2024

Updated Treatment Recommendation on Use of Cabotegravir and Rilpivirine for People With HIV From the IAS-USA Guidelines Panel

Paul E. Sax, MD[1]; Melanie A. Thompson, MD[2]; Michael S. Saag, MD[3]; et al

When supported by intensive follow-up and case management services, injectable cabotegravir and rilpivirine (CAB-RPV) may be considered for people with viremia who meet the criteria below when no other treatment options are effective due to a patient's persistent inability to take oral ART (rating AIIa under the conditions described).

- Unable to take oral ART consistently despite extensive efforts and clinical support
- High risk of HIV disease progression (CD4 cell count <200/μL or history of AIDS-defining complications)
- Virus susceptible to both CAB and RPV

If applicable, patients should also be referred for treatment of substance use disorder and/or mental illness.

JAMA®

Sax. JAMA. 2024; DHHS guidelines September 12, 2024

Updated: September 12, 2024
Reviewed: September 12, 2024

Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV

Virologic Failure

Updates made to the Virologic Failure section include the following:

- For people who experience virologic failure while on their first ARV regimen of a non-nucleoside reverse transcriptase inhibitor (NNRTI) plus two nucleoside reverse transcriptase inhibitors (NRTIs), a salvage regimen of DTG plus boosted darunavir can be used **(AI)**. This recommendation is based on data from the D^2EFT trial, a large randomized controlled trial comparing this regimen to a regimen of DTG plus two NRTIs.
- Some people with HIV cannot reach or maintain viral suppression on oral ART despite intensive adherence support. A complete regimen of long-acting injectable cabotegravir and rilpivirine (LA CAB/RPV) has been used in this population with some success, although long-term efficacy data are limited. Based on very limited data, the Panel recommends the use of LA CAB/RPV on a case-by-case basis in select individuals with persistent virologic failure despite intensive adherence support on oral ART, who have no evidence of resistance to CAB or RPV, and with shared decision-making between providers and people with HIV **(CIII)**. The Panel notes that people with HIV and their providers must be aware of the significant risk of developing resistance to NNRTIs, and particularly integrase strand transfer inhibitors (INSTIs) if virologic failure occurs on LA CAB/RPV. Such resistance may limit future treatment options and may also lead to HIV transmission.

D'après la communication orale de Gandhi et al. Long-acting treatment for non-virally suppressed individuals on cabotegravir + rilpivirine: real world evidence. HIV Glasgow 2024

O22

HIV DRUG THERAPY GLASGOW 2024

Cabotegravir and Rilpivirine concentrations and HIV-1 RNA suppression in male and female genital fluids and rectal tissue in people with HIV on antiretroviral therapy with long-acting intramuscular Cabotegravir plus Rilpivirine

Analuz Fernández[1], Sofia Scévola[1], Jordi Niubó[2], Craig Sykes[3], Amanda P Schauer[3], Camila Piatti[1], Sandra Morenilla[1], Alicia Sedó[1], Irene Soriano[1], Benito Garcia[1], Daniel Medina[1], Juan Tiraboschi[1], Maria Saumoy[1], Mackenzie L. Cottrell[3], Arkaitz Imaz[1]

1. HIV and STI Unit. Department of Infectious Diseases, Bellvitge University Hospital; Bellvitge Biomedical Research Institute; University of Barcelona, L'Hospitalet de Llobregat, Barcelona, Spain.
2. Department of Microbiology, Bellvitge University Hospital; Bellvitge Biomedical Research Institute; University of Barcelona, L'Hospitalet de Llobregat, Barcelona, Spain.
3. Eshelman School of Pharmacy, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA

Generalitat de Catalunya · Salut/Institut Català de la Salut/ Metropolitana Sud · Bellvitge Hospital Universitari · IDI BELL · Universitat de Barcelona

D'après la communication orale de Fernandez et al. Cabotegravir and rilpivirine concentrations and HIV-1 RNA suppression in male and female genital fluids and rectal tissue in people with HIV on antiretroviral therapy with long- acting intramuscular cabotegravir plus rilpivirin. O212 HIV Glasgow 2024

Objectives

1) To measure CAB and RPV concentrations in seminal plasma (SP), cervicovaginal fluid (CVF) and rectal tissue (RT) in PWH receiving LA CAB plus LA RPV administered intramuscularly every 2 months.

- To determine total drug and protein-free fraction
- To compare drug concentrations in genital fluids and RT with drug concentrations in blood plasma (BP)

2) To assess HIV-1 RNA levels in SP, CVF and rectal fluid (RF) in PWH receiving LA CAB plus LA RPV

D'après la communication orale de Fernandez et al. Cabotegravir and rilpivirine concentrations and HIV-1 RNA suppression in male and female genital fluids and rectal tissue in people with HIV on antiretroviral therapy with long- acting intramuscular cabotegravir plus rilpivirin. O212 HIV Glasgow 2024

Methods

- Single-centre study. Conducted between February 2023 and April 2024.
- **PARTICIPANTS SELECTION**:

Inclusion criteria

- Adults (≥ 18 years of age) with HIV-1
- Stable ART (≥6 months)
  - 3DR: 2 NRTI + 1 InSTI, NNRTI or bPI
  - 2DR: DTG/3TC or DTG/RPV
- Virologically suppressed (≥6 months)

Exclusion criteria

- History of resistance to CAB or RPV
- History of VF to InSTI or NNRTI
- HBV co-infection
- Pregnancy
- Severe renal impairment (eGFR <30 mL/min/1.73m^2)
- Severe hepatic impairment
- Grade 4 laboratory abnormality
- Ongoing malignancies
- Chronic anticoagulant therapy or hereditary coagulation or platelet disorders

- **STUDY POPULATION**:

  16 cisgender men (CGM)
  15 cisgender women (CGW)

- **STUDY TREATMENT**:

  ART was switched to oral CAB 30 mg + RPV 25 mg (oral lead-in) followed by intramuscular CAB 600 mg + RPV 900 mg at month 1 and 2, and every 2 months (+/- 7 days) thereafter.

D'après la communication orale de Fernandez et al. Cabotegravir and rilpivirine concentrations and HIV-1 RNA suppression in male and female genital fluids and rectal tissue in people with HIV on antiretroviral therapy with long- acting intramuscular cabotegravir plus rilpivirin. O212 HIV Glasgow 2024

Cabotegravir: total concentrations and protein-binding

CABOTEGRAVIR

CGM (n=16)	Median [range]	Coefficient of variation
Blood Plasma		
Total concentration	1063 ng/mL [537; 1900]	36.75%
Protein binding	99.94 % [99.85; 99.96]	0.03%
Seminal Plasma		
Total concentration*	23.3 ng/mL [10.1; 130]	96.11%
Protein binding	56.56 % [44.08; 77.17]	14.16%
Rectal Tissue		
Total concentration	90.02 ng/g [54.35; 138.77]	28.51%
Protein binding	71.66 % [46.04; 78.44]	12.35%

* n=14

SP/BP	RT/BP
0.02 [0.01; 0.11]	0.09 [0-06; 0.20]

Median [range]

CGW (n=15)	Median [range]	Coefficient of variation
Blood Plasma		
Total concentration	1470 ng/mL [1170; 2970]	30.36%
Protein binding	99.93% [99.88 ; 99.94]	0.02%
Cervicovaginal Fluid		
Total concentration	15.63 ng/mL [1.79; 428.23]	153.67%
Protein binding*	31.86% [12.86; 50.73]	32.38%

* n=12

CVF/BP
0.01 [0-00; 0.16]

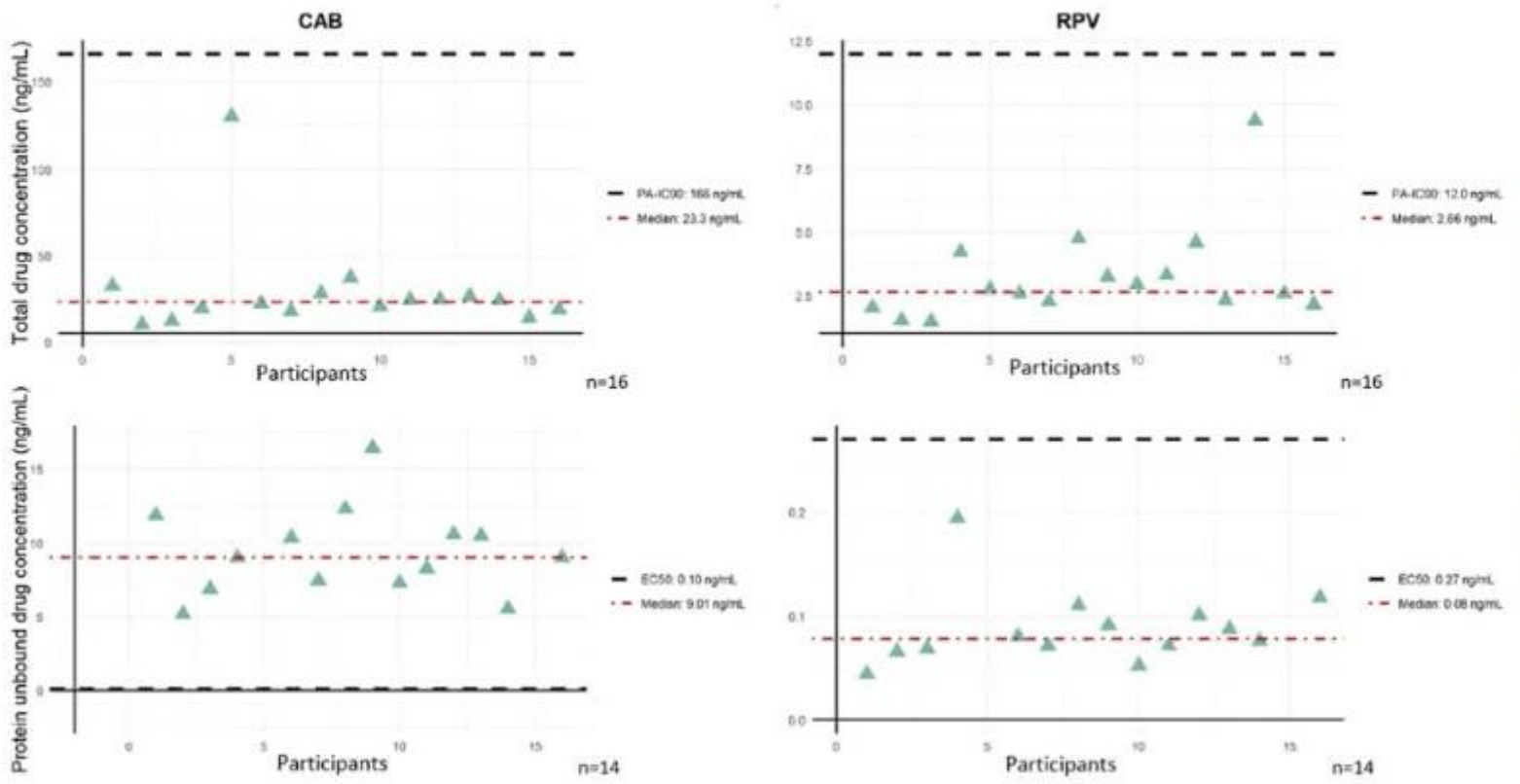
Median [range]

Drug concentration: C_{trough} (pre-dose, month 4)
Protein binding: %
PA-IC_{90}: 166 ng/mL

D'après la communication orale de Fernandez et al. Cabotegravir and rilpivirine concentrations and HIV-1 RNA suppression in male and female genital fluids and rectal tissue in people with HIV on antiretroviral therapy with long- acting intramuscular cabotegravir plus rilpivirin. O212 HIV Glasgow 2024

Seminal Plasma: Total and protein-unbound concentrations

- Protein-unbound CAB concentrations were higher than the EC_{50} value (median C_{trough} 90-fold above the EC_{50}).
- Protein-unbound RPV concentrations were lower than the EC_{50} value.



SP/BP for Total Drug*	
CABOTEGRAVIR	RILPIVIRINE
0.02 [0.01; 0.11]	0.08 [0.05; 0.12]

SP/BP for protein-unbound drug*	
CABOTEGRAVIR	RILPIVIRINE
13.04 [7.79;21.32]	1.79 [0.87; 4.90]

*Median [range]

D'après la communication orale de Fernandez et al. Cabotegravir and rilpivirine concentrations and HIV-1 RNA suppression in male and female genital fluids and rectal tissue in people with HIV on antiretroviral therapy with long- acting intramuscular cabotegravir plus rilpivirin. O212 HIV Glasgow 2024

Conclusions

- HIV-1 RNA suppression (below 20 copies/mL) was maintained in BP, genital and rectal fluids after switching to LA CAB plus LA RPV.
- The protein-unbound (active fraction) CAB concentrations highly exceeded the EC_{50} value for wild-type HIV-1 (0.10 ng/mL) in SP, RT and CVF, although the total concentrations were low compared to BP.
- The total and protein-unbound RPV concentrations exceeded the protein-adjusted IC_{90} (12 ng/mL) and the EC_{50} (0.27 ng/mL), respectively, in both RT and CVF.
- The RPV concentrations (both total and protein-unbound) observed in SP were lower than the PA-IC_{90} and the EC_{50} respectively.
- The treatment with LA CAB and LA RPV administered intramuscularly every 2 months was well tolerated. No grade 3-4 adverse events (including injection site reactions) were observed no participants discontinued treatment.

D'après la communication orale de Fernandez et al. Cabotegravir and rilpivirine concentrations and HIV-1 RNA suppression in male and female genital fluids and rectal tissue in people with HIV on antiretroviral therapy with long- acting intramuscular cabotegravir plus rilpivirin. O212 HIV Glasgow 2024

Once-Weekly Islatravir Plus Lenacapavir in Virologically Suppressed PWH: Week 48 Safety, Efficacy, and Metabolic Changes

Amy E. Colson[1], Gordon E. Crofoot[2], Peter J. Ruane[3], Moti N. Ramgopal[4], Alexandra W. Dretler[5], Ronald G. Nahass[6], Gary I. Sinclair[7], Mezgebe Berhe[8], Fadi Shihadeh[9], Shan-Yu Liu[9], Stephanie Klopfer[10], Sharline Madera[9], Hadas Dvory-Sobol[9], Martin S. Rhee[9], Elizabeth G. Rhee[10], Jared Baeten[9], Joseph Eron[11]

[1]Community Resource Initiative, Boston, Massachusetts, USA; [2]The Crofoot Research Center, Houston, Texas, USA; [3]Ruane Clinical Research, Los Angeles, California, USA; [4]Midway Immunology & Research Center, Fort Pierce, Florida, USA; [5]Metro Infectious Disease Consultants, Decatur, Georgia, USA; [6]IDCare, Hillsborough, New Jersey, USA; [7]Prism Health North Texas, Dallas, Texas, USA; [8]North Texas Infectious Diseases Consultants, Dallas, Texas, USA; [9]Gilead Sciences, Foster City, California, USA; [10]Merck & Co., Inc., Rahway, New Jersey, USA; [11]University of North Carolina, Chapel Hill, North Carolina, USA

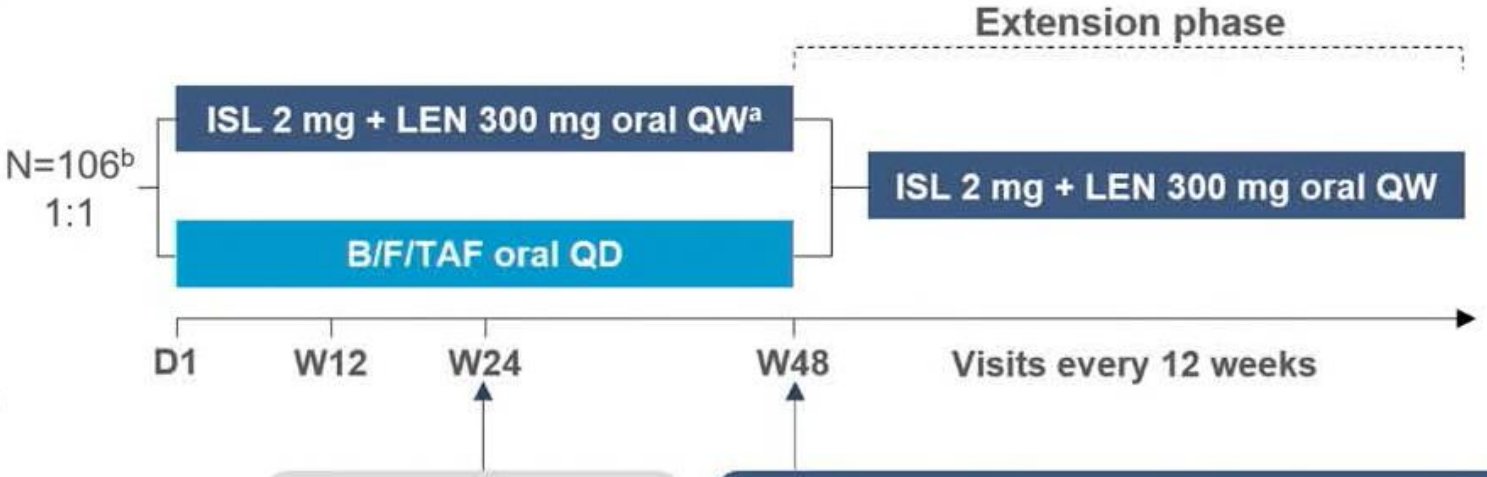
HIV Drug Therapy Glasgow 2024, November 10–13, Glasgow, United Kingdom

D’après la communication orale de Colson et al. Once-weekly islatravir plus lenacapavir in virologically suppressed PWH: week 48 safety, efficacy, and metabolic changes. O21. HIV Glasgow 2024

Methods

A Phase 2, Open-label, Active-Controlled Study in Virologically Suppressed PWH

Eligibility criteria
- Aged ≥18 years
- On B/F/TAF for >6 months
- HIV-1 RNA <50 c/mL for >6 months
- No history of virologic failure
- CD4+ T-cell count ≥350 cells/µl
- Lymphocyte count ≥900 cells/µl
- No HBV infection



Primary endpoint:[1]
- Proportion with HIV-1 RNA ≥50 c/mL at Week 24 per FDA Snapshot Algorithm

Secondary endpoints included in this presentation:
- Proportion with HIV-1 RNA ≥50 c/mL at Week 48
- Proportion with HIV-1 RNA <50 c/mL at Week 48
- Change from baseline in CD4+ T-cell count
- AEs leading to study drug discontinuation

Other assessments:
- Change in BMI, body weight, and adherence

[a]600 mg of LEN was given on Day 1 and Day 2 for pharmacologic loading. [b]Randomised, N=106; dosed, n=104.
AE, adverse event; **B/F/TAF**, bictegravir/emtricitabine/tenofovir alafenamide; **BMI**, body mass index; **c/mL**, copies/ml; **D**, Day; **FDA**, Food and Drug Administration; **HBV**, hepatitis B virus; **ISL**, islatravir; **LEN**, lenacapavir; **PWH**, people with HIV-1; **QD**, daily; **QW**, weekly; **W**, Week.
1. Colson A, et al. CROI 2024; Abstract 208.

D'après la communication orale de Colson et al. Once-weekly islatravir plus lenacapavir in virologically suppressed PWH: week 48 safety, efficacy, and metabolic changes. O21. HIV Glasgow 2024

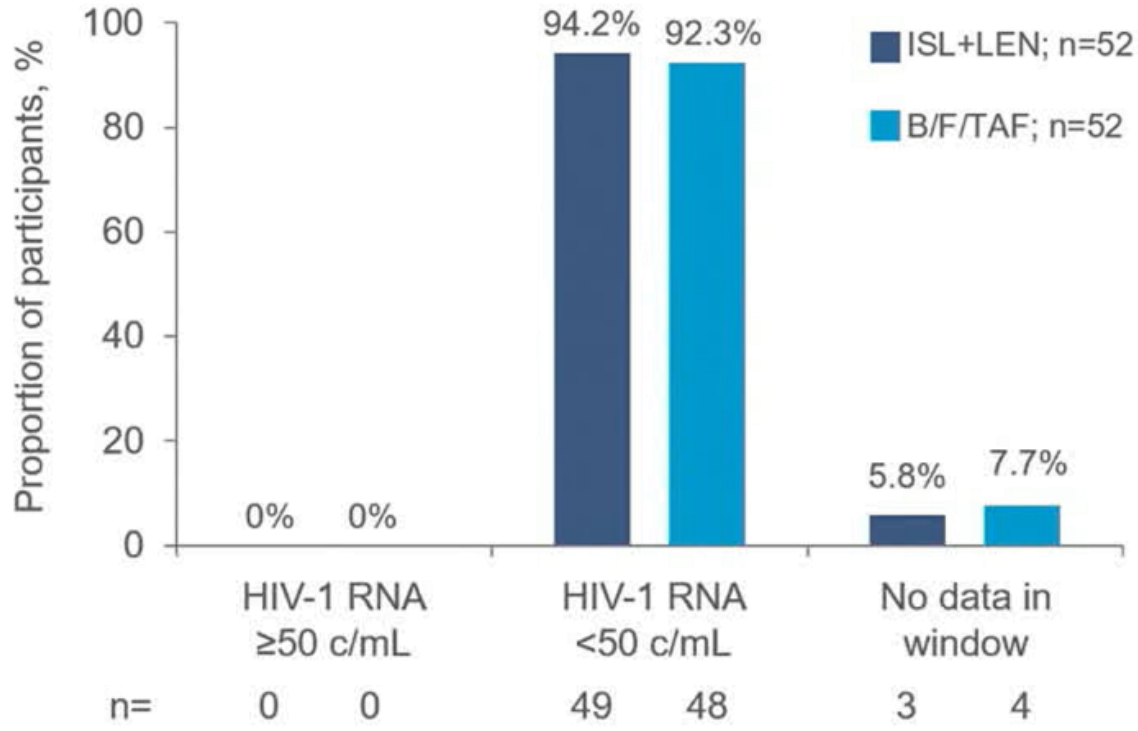
Baseline demographic and disease characteristics

	ISL+LEN (n=52)	B/F/TAF (n=52)	Total (N=104)
Median (range) age, years	40 (28–67)	40 (26–76)	40 (26–76)
Assigned female at birth, n (%)	10 (19.2)	9 (17.3)	19 (18.3)
Gender identity, n (%)			
Transgender female	1 (1.9)	0	1 (1.0)
Non-binary/third gender	0	1 (1.9)	1 (1.0)
Race, n (%)			
White	25 (48.1)	27 (51.9)	52 (50.0)
Black	21 (40.4)	16 (30.8)	37 (35.6)
Asian	2 (3.8)	1 (1.9)	3 (2.9)
American Indian or Alaska Native	1 (1.9)	2 (3.8)	3 (2.9)
Native Hawaiian or Pacific Islander	0 (0)	1 (1.9)	1 (1.0)
Other	3 (5.8)	5 (9.6)	8 (7.7)
Hispanic or Latinx ethnicity, n (%)	13 (25.0)	17 (32.7)	30 (28.8)
Mean (SD) CD4+ T-cell count, cells/µL	755 (223.6)	818 (271.3)	786 (249.5)
Mean (SD) lymphocyte count x 10^3 cells/µL	1.94 (0.445)	1.95 (0.652)	1.94 (0.556)
Median (IQR) body weight, kg	79.3 (70.4–87.4)	83.2 (76.1–92.5)	80.5 (74.4–88.7)
Median (IQR) BMI, kg/m^2	26.9 (23.8–30.0)	27.2 (25.5–29.3)	27.1 (24.5–29.4)

B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; **BMI**, body mass index; **IQR**, interquartile range; **ISL**, islatravir; **LEN**, lenacapavir.

D'après la communication orale de Colson et al. Once-weekly islatravir plus lenacapavir in virologically suppressed PWH: week 48 safety, efficacy, and metabolic changes. O21. HIV Glasgow 2024

Virologic Outcomes at Week 48 by FDA Snapshot Algorithm



Participants with no data in window:

ISL+LEN (n=3)

- Two participants discontinued due to AEs not related to study drug
- One participant discontinued due to other reasons not related to study drug
- All participants had HIV-1 RNA <50 c/mL at study discontinuation

B/F/TAF (n=4)

- Three participants discontinued due to other reasons not related to study drug and had HIV-1 RNA <50 c/mL at study discontinuation
- One participant had missing data during window, but remained on study drug

Participants in both treatment groups maintained high rates of virologic suppression

AE, adverse event; **B/F/TAF**, bictegravir/emtricitabine/tenofovir alafenamide; **c/mL**, copies/mL; **FDA**, Food and Drug Administration; **ISL**, islatravir; **LEN**, lenacapavir.

D'après la communication orale de Colson et al. Once-weekly islatravir plus lenacapavir in virologically suppressed PWH: week 48 safety, efficacy, and metabolic changes. O21. HIV Glasgow 2024

Adverse Events

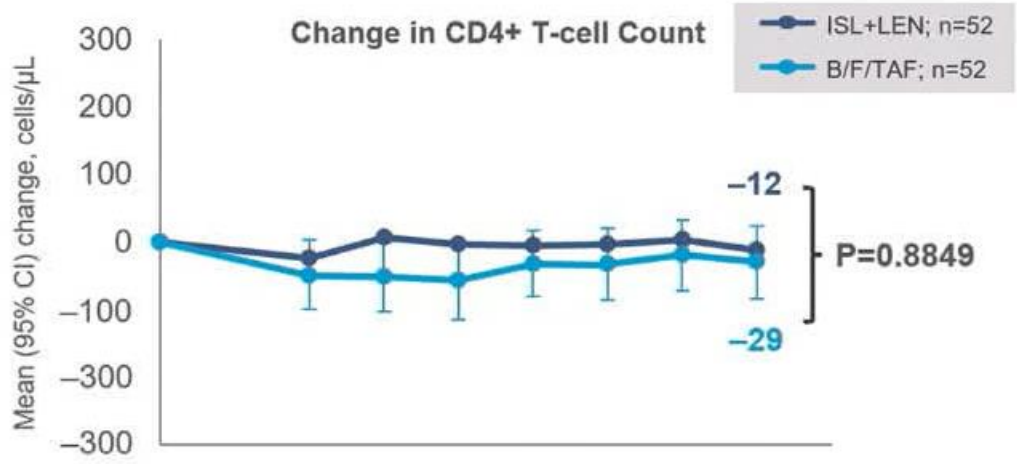
Participants, n (%)	ISL+LEN (n=52)	B/F/TAF (n=52)
Any AE	42 (80.8)	40 (76.9)
Treatment-related AE	10 (19.2)	3 (5.8)
Grade 1 or 2	10 (19.2)	3 (5.8)
≥2 participants in ISL+LEN group		
Dry mouth	2 (3.8)	0
Nausea	2 (3.8)	0
Grade 3 or 4	0	0
Serious AE	3 (5.8)[a]	0
Treatment-related	0	0
AE leading to study drug discontinuation	2 (3.8)[b]	0
Treatment-related	0	0

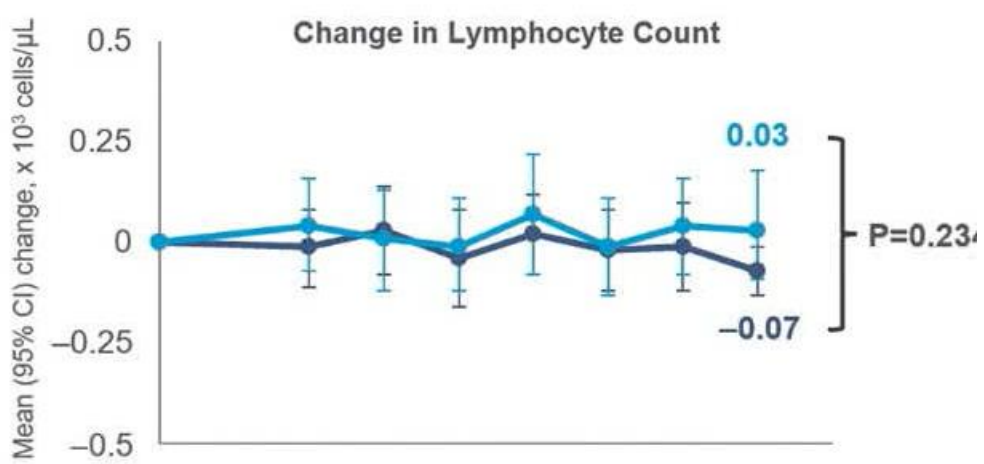
No Grade 3 or higher AEs, serious AEs, or AEs leading to discontinuation were considered related to the study drug by the investigator

[a]Serious AEs included large intestine perforation and renal colic (in the same participant), pneumonia, and neurologic anesthetic complication. [b]Large intestine perforation and renal colic, n=1; acute hepatitis B infection, n=1 (both participants had HIV-1 RNA <50 c/mL at study discontinuation).
AE, adverse event; **B/F/TAF**, bictegravir/emtricitabine/tenofovir alafenamide; **c/mL**, copies/mL; **ISL**, islatravir; **LEN**, lenacapavir.

D'après la communication orale de Colson et al. Once-weekly islatravir plus lenacapavir in virologically suppressed PWH: week 48 safety, efficacy, and metabolic changes. O21. HIV Glasgow 2024

CD4+ T-cell and Lymphocyte Count Changes Through Week 48





Mean Values	BL	W12	W18	W24	W30	W36	W42	W48
ISL+LEN	755	732	766	755	754	756	761	746
B/F/TAF	818	758	767	761	785	783	797	787

Mean Values	BL	W12	W18	W24	W30	W36	W42	W48
ISL+LEN	1.94	1.94	1.98	1.92	1.96	1.94	1.93	1.88
B/F/TAF	1.95	1.99	1.97	1.96	2.03	1.96	2.00	1.99

- There were no significant differences between groups in mean change from baseline in CD4+ T-cell or lymphocyte counts at Week 48
- No participants discontinued due to a decrease in CD4+ T-cell or lymphocyte counts

B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; **BL**, baseline; **ISL**, islatravir; **LEN**, lenacapavir; **W**, Week.

D'après la communication orale de Colson et al. Once-weekly islatravir plus lenacapavir in virologically suppressed PWH: week 48 safety, efficacy, and metabolic changes. O21. HIV Glasgow 2024

P058

Long acting cabotegravir plus lenacapavir as a fully injectable maintenance antiretroviral regimen in people with HIV with adherence issues

Romain Palich,[1] Romain Manchon,[2] Jérémy Zeggagh,[2] Elisabete Gomes Pires,[2] Marc Wirden,[3] Marianne Burgard,[4] Sophie Seang,[1] Marc-Antoine Valantin,[1] Gilles Peytavin,[5] Claudine Duvivier[2,6]

1. Sorbonne Université, Pitié-Salpêtrière hospital, AP-HP, Infectious Diseases Department; Pierre Louis Epidemiology and Public Health institute (iPLESP), INSERM 1136, Paris, France. 2. Paris Cité University, Necker hospital, AP-HP; IHU Imagine; Necker-Pasteur Infectiology Center, Paris, France. 3. Sorbonne Université, Pitié-Salpêtrière hospital, AP-HP, Virology Department; Pierre Louis Epidemiology and Public Health institute (iPLESP), INSERM 1136, Paris, France. 4. Paris Cité University, Necker hospital, AP-HP, Virology Department, Paris, France. 5. Paris Cité University, Bichat-Claude Bernard hospital, AP-HP; INSERM, 1137, IAME, Paris, France. 6. INSERM U1016, CNRS UMR8104, Institut Cochin, Paris France.

Conclusion

- **LAI-CAB plus LAI-LEN maintained effective viral suppression with good Tolerability**
- Despite the expected moderate injection site reactions, all patients expressed a preference for this treatment over oral ART.
- To improve the administration of this full injectable strategy, it would be interesting to administer LAI-CAB at months 0, 1 and 2, and then every 2 months to coincide with
- LEN injections every 6 months
- **It holds great promise for vulnerable PLWH struggling with oral ART adherence, particularly when RPV is not an option anymore, and merits prospective evaluation in a large, randomised trial**

T-cell Homeostasis Parameters Following Switch to Injectable Cabotegravir plus Rilpivirine in Virally-Suppressed People Living with HIV (PLWH)

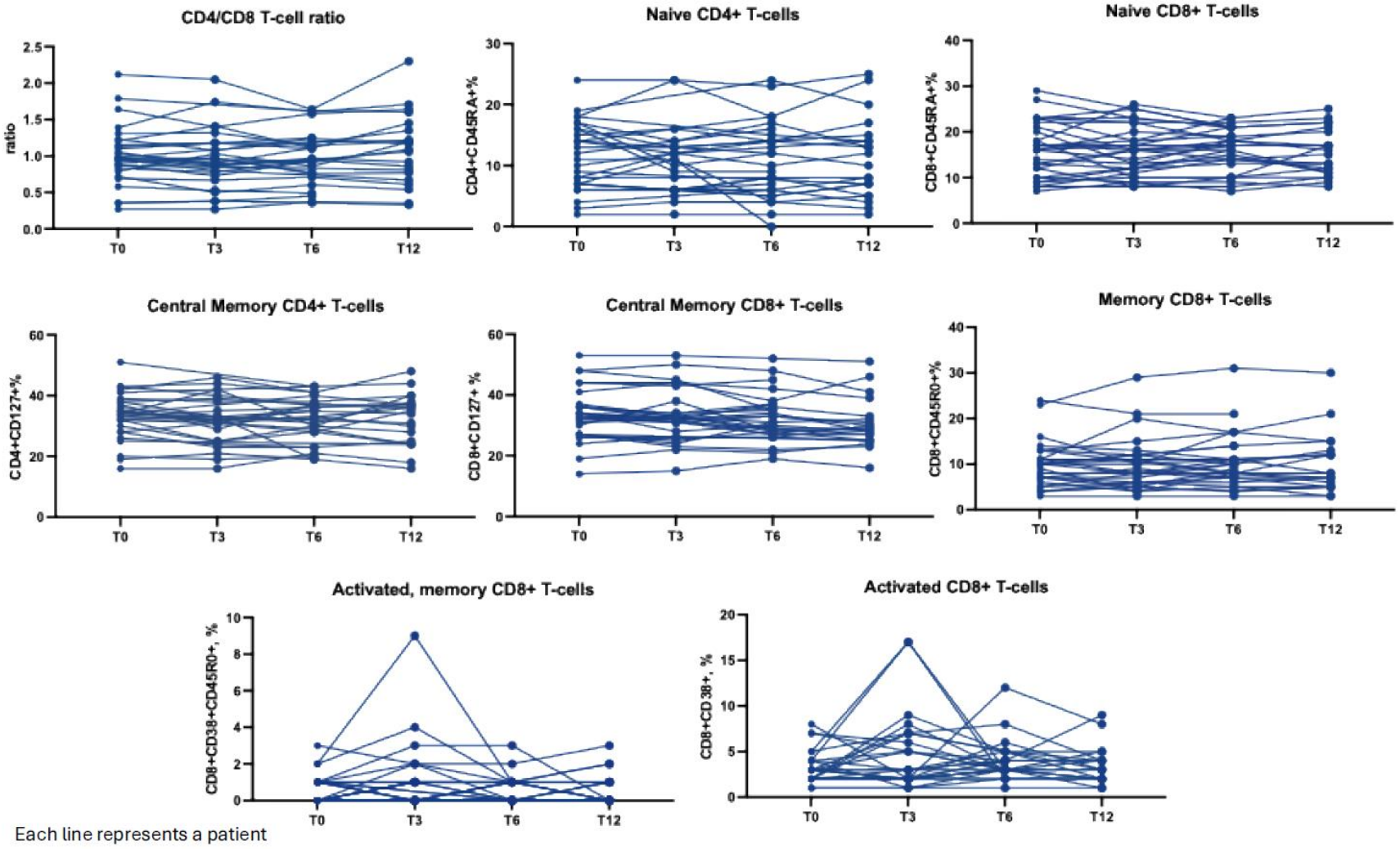
Camilla Tincati*[1,2], Leonardo Francesco Rezzonico[1], Andrea Santoro[1], Emanuela Ferrante[1], Teresa Bini[2], Lidia Gazzola[2] and Giulia Marchetti [1,2]

[1]Department of Health Sciences, University of Milan, Italy
[2]Clinic of Infectious Diseases, ASST Santi Paolo e Carlo, Milan, Italy

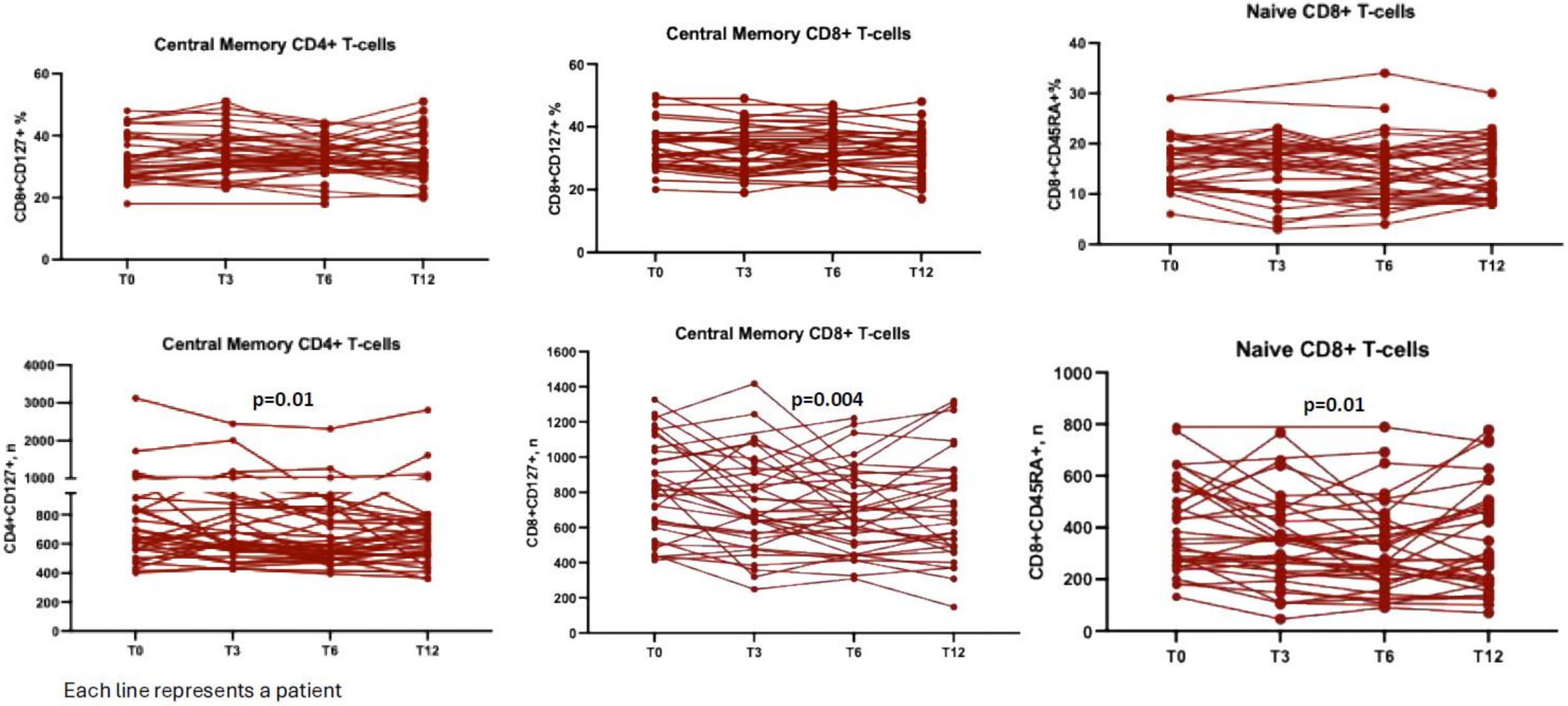
P103

*camilla.tincati@unimi.it

T-cell homeostasis parameters in individuals switiching to LAI from 3-DR oral cART



T-cell homeostasis parameters in individuals switiching to LAI from 2-DR oral cART (top: percentage values; bottom: absolute values)



D'après le poster de Tincati et al. T-cell Homeostasis Parameters Following Switch to Injectable Cabotegravir plus Rilpivirine in Virally-Suppressed People Living with HIV (PLWH). P103. HIV Glasgow 2024

Conclusion

- Switching to injectable CAB/RPV did not have major effects on T-cell homeostasis
- Central memory CD4+ and CD8+ T-cells as well as naïve CD8+ cells show a decreasing trend in individuals switching from oral 2-DR, the mechanism(s) by which long-acting injectables may influence T-cell homeostasis in the long-term needs careful investigation

D’après le poster de Tincati et al. T-cell Homeostasis Parameters Following Switch to Injectable Cabotegravir plus Rilpivirine in Virally-Suppressed People Living with HIV (PLWH). P103. HIV Glasgow 2024

Poster
P078

Use of long-acting Cabotegravir and Rilpivirine in a real-life setting: 12-month results of virological outcome, adherence, safety, durability, in the ANRS CO3 AquiVIH-NA Cohort-France.

M. Hessamfar[1,2], O. Leleux[2], A. Peyrouny-Mazeau[2], C. Krzyzanowsky[1], G. Le Moal[3], D. Neau[4], H. Ferrand[5], A. Desclaux[4], E. Lazaro[6], P. Duffau[7], Y. Gérard[8], M-A Vandenhende[9], F. Bonnet[1,2].

[1]Service de Médecine Interne et Maladies Infectieuses, Hôpital Saint-André, Centre Hospitalier Universitaire (CHU) de Bordeaux, Bordeaux, France ; [2]Bordeaux Population Health Research Center, INSERM U1219, CIC-EC 1401, Univ. Bordeaux - ISPED, Bordeaux, France ; [3]Service de Maladies Infectieuses et Tropicales, Centre Hospitalier Universitaire (CHU) de Poitiers, Poitiers, France ; [4]Service de Maladies Infectieuses et Tropicales, Hôpital Pellegrin, Centre Hospitalier Universitaire (CHU) de Bordeaux, Bordeaux, France ; [5]Service de Maladies Infectieuses et Médecine vasculaire, Centre Hospitalier de Libourne, Libourne, France ; [6]Service de Médecine Interne et Maladies Infectieuses, Hôpital Haut-Lévèque, Centre Hospitalier Universitaire (CHU) de Bordeaux, Pessac, France ; [7]Service de Médecine Interne et Immunologie Clinique, Hôpital Saint-André, Centre Hospitalier Universitaire (CHU) de Bordeaux, Bordeaux, France ; [8]Service de Maladies Infectieuses, Centre Hospitalier de Dax, Dax, France ; [9]Service de Médecine Interne, Hôpital Pellegrin, Centre Hospitalier Universitaire (CHU) de Bordeaux, Bordeaux, France.

HIV DRUG THERAPY GLASGOW 2024

P081

LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE IN HIV INDIVIDUALS WITH A BMI OVER 30: A REAL-WORLD STUDY (RELATIVITY COHORT)

Jesús Troya, Luis Morano, Jose Ignacio Bernardino, Luis Buzón, Roberto Pedrero-Tomé, María José Galindo, Miguel Torralba, Noemí Cabello, María García, Mar Masiá, Miguel Alberto de Zárraga, Alfonso Cabello, Maria Aguilera, Álvaro Cecilio, Alberto Díaz de Santiago[15], María Ángeles Garcinuño, Enrique Bernal, Mireia Santacreu, Ruth Calderón, María Jesús Vivancos, Teresa Omiste, Eva Ferreira, Juan Emilio Losa, Josefa Soler, María Antonia Sepúlveda, María del Mar García, on behalf of the ***RELATIVITY PROJECT GROUP***

Comorbidités & VIH

Fabrice BONNET, Bordeaux

P277

Comparison of 4 Frailty scores to predict adverse health outcomes and mortality in people living with HIV aged 70 years and more (ANRS EP66 SEPTAVIH study)

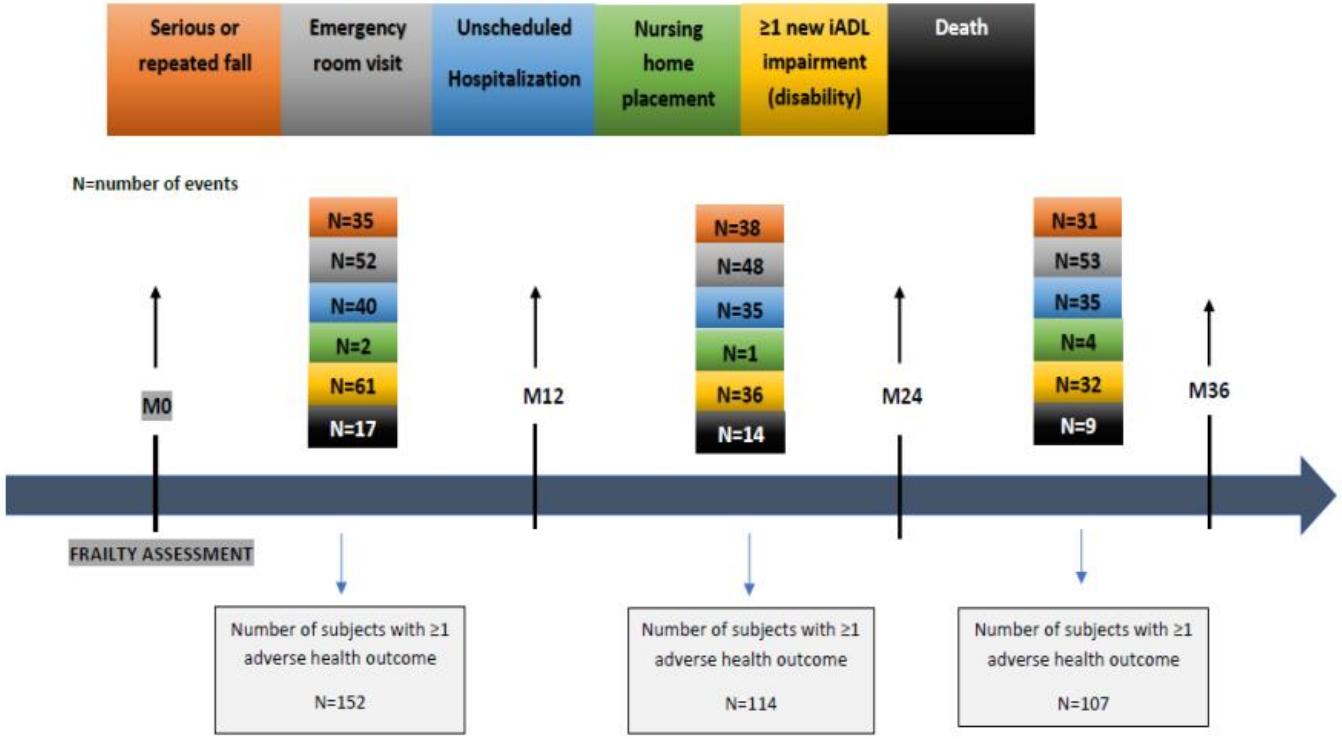
ALLAVENA Clotilde[1] ; ABULIZI Diane[2] ; BLAIN Hubert[3] ; ADRIANTSOANIRINA Valérie[2] ; ABGRALL Sophie[4] ; KARMOCHKINE Marina[5] ; KATLAMA Christine[6] ; PREVILON Miresta[7] ; CABIE André[8] ; BONNET Fabrice[9] ; MEYER Laurence[2,10] ; MAKINSON Alain[11]

1-Infectious Diseases Department INSERM EA1413, Nantes University Hospital, NANTES, France ; 2-INSERM CESP U1018, Paris-Saclay University, Le Kremlin-Bicêtre, France ; 3-Geriatrics Department, Montpellier University Hospital, Montpellier, France ; 4-Internal Medicine Department, Hop Antoine Béclère AP-HP, Clamart, France ; 5-Infectiology, Hôpital Hôtel Dieu AP-HP, Paris, France ; 6-Infectious Diseases Department, Hôpital Pitié-Salpétrière AP-HP, Paris, France ; 7-Infectious Diseases Department, Hôpital Saint Louis AP-HP, Paris, France ; 8-Infectious Diseases Department, Martinique University Hospital, Fort de France, France ; 9-Infectious Diseases Department, Bordeaux University Hospital, Bordeaux, France ; 10-Public Health Department, Bicêtre University Hospital AP-HP, Le Kremlin-Bicêtre, France ; 11-Infectious Diseases department, Montpellier University Hospital, Montpellier, France

Results

Adverse Health Outcomes at M12, M24 and M36

- 510 PLWH, mostly male (81.4%) with a median age of 73 years a median HIV infection duration of 22.7 years were included;
- 13% were classified as frail using FRIED, 9% using FRAIL, 7% using SOF and 26% using the HAS scores
- During the 36 month follow up, 40 participants (7.9%) died and 254 participants (50%) had at least one adverse health outcome



D'après le poster d'Allavena et al. Comparison of 4 Frailty scores to predict adverse health outcomes and mortality in people living with HIV aged 70 years and more (ANRS EP66 SEPTAVIH study. P277. HIV Glasgow 2024

Association of frailty status assessed with FRIED phenotype, frail score, SOF index and HAS questionnaire

And adverse heakth outcomes of mortality over 36 months

Frailty score at Baseline		Log-Binomial regression	
	Relative Risk	[95% CI]	p-value
FRIED			
Robustness (n=84)	1.0	[reference]	
Prefrailty (n=211)	1.01	[0.85-1.20]	0.89
Frailty (n=39)	1.25	[1.02-1.52]	0.03
FRAIL			
Robustness (n=166)	1.0	[reference]	
Prefrailty (n=116)	1.30	[1.11-1.52]	0.001
Frailty (n=25)	1.66	[1.47-1.88]	<0.001
SOF			
Robustness (n=97)	1.0	[reference]	
Prefrailty (n=182)	1.10	[0.93-1.31]	0.28
Frailty (n=20)	1.23	[0.95-1.60]	0.12
HAS			
No frailty (n=261)	1.0	[reference]	
Frailty (n=94)	1.41	[1.26-1.59]	<0.001

And mortality over 36 months

Frailty score at Baseline		Cox model	
	Hazard ratio	[95% CI]	p-value
FRIED			
Robustness (n=109)	1.0	[reference]	
Prefrailty (n=298)	2.35	[0.81-6.79]	0.11
Frailty (n=61)	5.37	[1.65-17.47]	0.005
FRAIL			
Robustness (n=231)	1.0	[reference]	
Prefrailty (n=155)	4.69	[1.99-11.02]	<0.0001
Frailty (n=37)	4.54	[1.33-15.53]	0.016
SOF			
Robustness (n=138)	1.0	[reference]	
Prefrailty (n=252)	1.60	[0.67-3.77]	0.29
Frailty (n=30)	2.84	[0.83-9.72]	0.10
HAS			
No frailty (n=370)	1.0	[reference]	
Frailty (n=129)	5.00	[2.65-9.41]	<0.001

D'après le poster d'Allavena et al. Comparison of 4 Frailty scores to predict adverse health outcomes and mortality in people living with HIV aged 70 years and more (ANRS EP66 SEPTAVIH study. P277. HIV Glasgow 2024

HAS questionnaire

REPÉRAGE			
	Oui	Non	Ne sait pas
Votre patient vit-il seul ?	❑	❑	❑
Votre patient a-t-il perdu du poids au cours des 3 derniers mois ?	❑	❑	❑
Votre patient se sent-il plus fatigué depuis ces 3 derniers mois ?	❑	❑	❑
Votre patient a-t-il plus de difficultés pour se déplacer depuis ces 3 derniers mois ?	❑	❑	❑
Votre patient se plaint-il de la mémoire ?	❑	❑	❑
Votre patient a-t-il une vitesse de marche ralentie (plus de 4 secondes pour parcourir 4 mètres) ?	❑	❑	❑

Si vous avez répondu OUI à une de ces questions :

Votre patient vous paraît-il fragile : ❑ OUI ❑ NON

Si oui, votre patient accepte-t-il la proposition d'une évaluation de la fragilité en hospitalisation de jour : ❑ OUI ❑ NON

D'après le poster d'Allavena et al. Comparison of 4 Frailty scores to predict adverse health outcomes and mortality in people living with HIV aged 70 years and more (ANRS EP66 SEPTAVIH study. P277. HIV Glasgow 2024

Conclusions

- This study is one of the first one to compare different scores of frailty in a geriatric population living with HIV aged 70 year or more on the occurrence of adverse health outcomes over 3 years
- FRIED phenotype FRAIL score and HAS tools but not SOF index strongly predicted the risk of adverse health outcomes or mortality in a geriatric population living with HIV
- Mortality over 36 months was strongly associated with frailty status when assessed with FRIED phenotype questionnaire
- These results are reassuring concerning the choice of both the FRAIL EACS guidelines V 12 0 and the HAS questionnaire in the French guidelines as a screening test for frailty in an elderly population living with HIV

D'après le poster d'Allavena et al. Comparison of 4 Frailty scores to predict adverse health outcomes and mortality in people living with HIV aged 70 years and more (ANRS EP66 SEPTAVIH study. P277. HIV Glasgow 2024

Use of lipid-lowering drugs, even when associated with polypharmacy, reduces risk of hospitalization in PWH >50 years

Jovana Milic[1], Alessandra Carobbio[1], Antonia Pugliese[2], Pierluigi de Cosmo[3], Lorenzo Federici[1], Federico Motta[1], Filippo Calandra Buonaura[1], Matteo Mantovani[1], Francesca Gandolfi[2], Chiara Mussi[1], Cristina Mussini[1], **Giovanni Guaraldi[1]**

1 University of Modena and Reggio Emilia, Modena, Italy; 2 Distribuzione Diretta AUSL Modena, Dipartimento Farmaceutico Interaziendale, Modena, Italy; 3 Infologic Srl, Padova, Italy;

P331

Comparison between PWH and PWoH

Methods

- This was a **cross-sectional study** of ART experienced PWH and PWoH > 50 years in Modena, Italy. **Inclusion criteria were:**
  - being resident and having a general practitioner in Modena;
  - taking at least one drug class prescribed for chronic use according to Anatomical Therapeutic Chemical (ATC) Classification (including ART for PWH).
- Groups were **matched in 1:10 ratio** for age and sex.

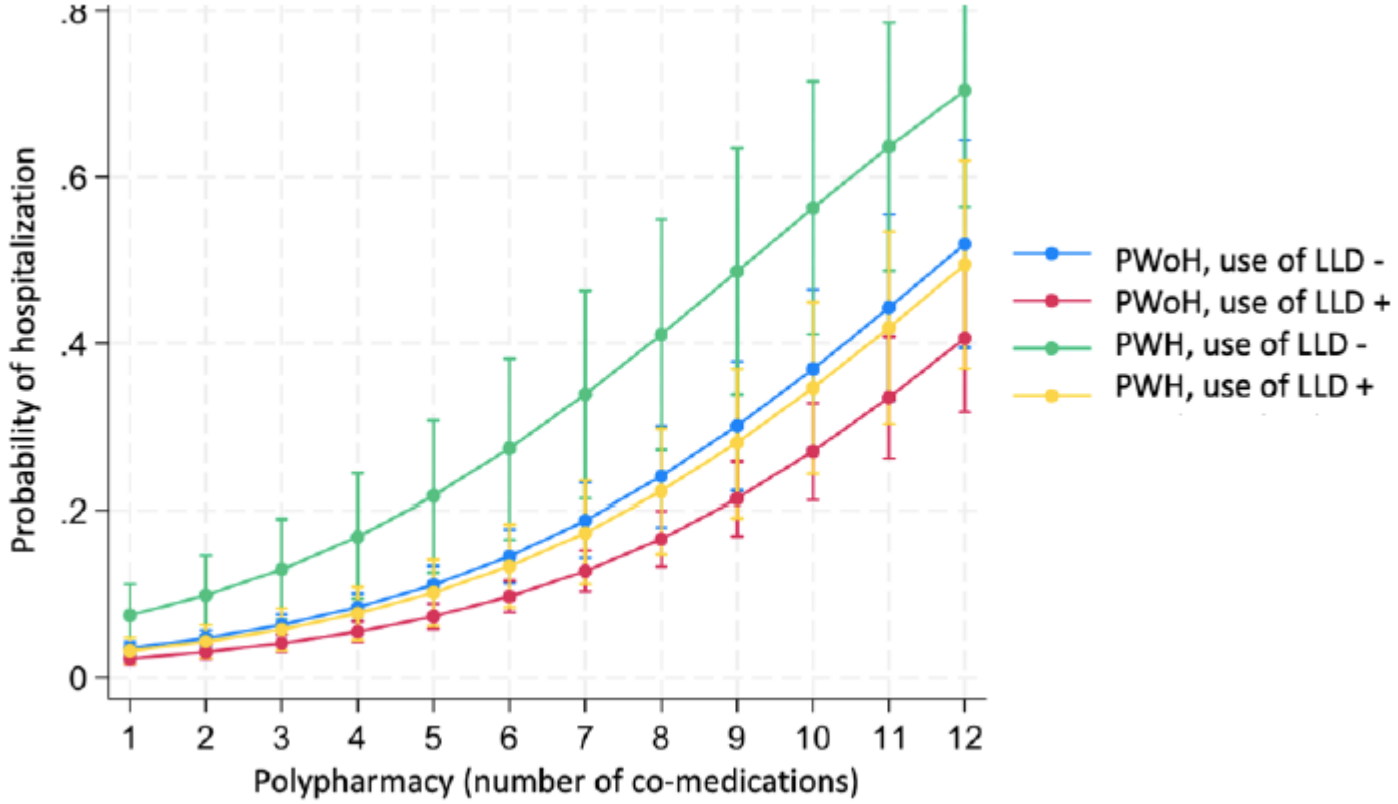
- **317 PWH and 3170 PWoH were included, median age was 60 years, 2409 (69.1%) were males**

- **In adjusted model, PWH were at higher risk of 1-year hospitalization when compared to PWoH (OR= 2.50; 95% CI = 1.70-3.52; p<0.001)**

	People with HIV (PWH); N = 317	People without HIV (PWoH); N = 3170	p
Male sex, N (%)	219 (69.1%)	2190 (69.1%)	1.00
Age, years, median (Q1, Q3)	60.0 (57.0-65.0)	60.0 (57.0-65.0)	1.00
Polypharmacy, N (%)	100 (31.5%)	396 (12.5%)	**<0.001**
Use of LLD, N (%)	194 (61.2%)	1321 (41.7%)	**<0.001**
Use of proton-pump inhibitors, N (%)	66 (20.8%)	697 (22.0%)	0.63
Use of antidepressants, N (%)	52 (16.4%)	297 (9.4%)	**<0.001**
Use of antipsychotics, N (%)	13 (4.1%)	81 (2.6%)	0.11
Hospitalization, N (%)	45 (14.2%)	199 (6.3%)	**<0.001**

D'après le poster Guaraldi. Use of lipid-lowering drugs, even when associated with polypharmacy, reduces risk of hospitalization in PWH >50 years. P331. HIV Glasgow 2024

Adjusted predictions for hospitalization according to polypharmacy, HIV status and use of LLD



D'après le poster Guaraldi. Use of lipid-lowering drugs, even when associated with polypharmacy, reduces risk of hospitalization in PWH >50 years. P331. HIV Glasgow 2024

Conclusion

- **Prevalence of polypharmacy was higher in PWH and was associated with an increased risk for hospitalization**
- **Use of LLD, even when associated with polypharmacy, significantly reduced probability of hospitalization, highlighting the importance of cardiovascular disease prevention and appropriate prescription in PWH**

D'après le poster Guaraldi. Use of lipid-lowering drugs, even when associated with polypharmacy, reduces risk of hospitalization in PWH >50 years. P331. HIV Glasgow 2024

Evaluation of T-cell immunosenescence markers in virologically suppressed people living with HIV aged over 60 years on BIC/FTC/TAF or DTG/3TC: the Collateral study

Vassallo M**, Ticchioni M***, Chirio D*, Sadou Ami***, Cua E*, Ceppi C*, Ferrando S*, Naqvi A*, Prouvost-Keller B*, Mangin-Rattana S*, Ameil L*, Godemert M****, Carles M* & Durant J*.

Infectious diseases Department Nice France* Internal medicine/Infectious diseases Department Cannes France** Department of immunology Nice France*** Clinical research Department****

P282

Presenting author E-mail:

Méthodes

Study design and participants

- Collateral is a multicentre on-going French prospective cohort study, performed in Nice and Cannes, France. Inclusion criteria were participants over 40 years of age or over 10 years on ART, on stable and successful ART with either
- Bictegravir/Emtricitabine/Tenofovir alafenamide (BIC/FTC/TAF) or Dolutegravir/Lamivudine (DTG/3TC) for at least 6 months

Cellular markers of immune activation and senescence

- For each PWH and controls, multi-color flow cytometry on freshly isolated PBMCs was performed, allowing the identification of the following CD4+ and CD8+ subsets: naïve (N), central memory (CM), effector memory (EM) and terminally differentiated effector memory (TEMRA) cells. Indeed, on the basis of the expression of two surface molecules, CD45RA and CCR7, T-cells can be divided into four subsets, with the following characteristics: CD45RA+CCR7+ for N cells, CD45RACCR7+ for CM, CD45RA-CCR7- for EM and CD45RA+CCR7- for TEMRA [7]
- Moreover, according to previous works, cells double expressing the co-inhibitory receptor killer-cell lectin like receptor 1 (KLRG-1) and CD57 markers were considered as senescent [4, 8].

D'après le poster de Vassallo et al. Evaluation of T-cell immunosenescence markers in virologically suppressed people living with HIV aged over 60 years on BIC/FTC/TAF or DTG/3TC: the Collateral study. P282. HIV Glasgow 2024

Characteristics of subjects included and markers of immunosenescence

	HIV-neg mean±sd n = 5	DTG/3TC mean±sd n = 26	BIC/FTC/TAF mean±sd n = 23	*p* Dual ART vs Triple ART
Demographic and background characteristics				
Age	66.4±2.07	70±6.7	69±6.7	0.84
Years from HIV diagnosis	NA	28.03±9.1	29.7±7.1	0.47
Years on ART	NA	23.1±7.8	24±6.4	0.68
CD4 at inclusion (cc/mm3)	967±126	636±302	524±243	0.165
CD4/CD8 ratio	2.65+±1.36	0.56±0.17	0.72±0.35	0.055*
Number of comorbidies	NA	2.50±1.22	2.0±1.27	0.12
Markers of immunosenescence				
SEN-CD4+	15.6±22.7	61.1± 46.3	24.7±35.1	**0.05**
SEN-CD8+	147±224	401±182	255±128	**0.039***
SEN-CD4-38+	19±23	54±42	17±18	**0.01***
SEN-TEMRA-CD4+	10±9	28±35	5.6±6.3	**0.04***
SEN-EM-CD4+	6±10	28+-24	16+-27	0.07
SEN-CD8-38+	133±208	297±138	173±120	**0.03***
SEN-TEMRA-CD8+	81.2±155	237±119	98.1±98.0	**0.02***
SEN-EM-CD8+	38±46	108±170	36±26	0.06
CD8-TEMRA	109±207	299+-168	124±109	**0.007***
CD4-TEMRA	28.2±30.8	36.2±39.8	11.9±11.2	0.056*

D'après le poster de Vassallo et al. Evaluation of T-cell immunosenescence markers in virologically suppressed people living with HIV aged over 60 years on BIC/FTC/TAF or DTG/3TC: the Collateral study. P282. HIV Glasgow 2024

Conclusions

- In PLWH aged over 60 years with CD4 nadir <200 cells/mm3, we found lower levels of immunosenescence markers on BIC/FTC/TAF compared to DTG/3TC

- Our results suggest that past CD4 count should be considered as criteria for treatment decision choice between 2DR and 3DR in order to reduce risks of age-associated complications

D'après le poster de Vassallo et al. Evaluation of T-cell immunosenescence markers in virologically suppressed people living with HIV aged over 60 years on BIC/FTC/TAF or DTG/3TC: the Collateral study. P282. HIV Glasgow 2024

P048 - Changes in patient-reported neuropsychological outcomes in virologically suppressed persons with HIV switching to DTG/3TC or BIC/FTC/TAF: a substudy of the PASO-DOBLE randomized clinical trial

Lucio Garcia-Fraile [1], Mar Masia [2], Maria J. Crusells [3], Pere Domingo [4], Adria Curran [5], Roberto Guerri-Fernandez [6], Enrique Bernal [7], Joaquin Bravo [8], Boris Revollo [9], Juan Macias [10], Juan M. Tiraboschi [11], Rocio Montejano [12], Concepcion Amador [13], Miguel Torralba [14], Dolores Merino [15], Vicens Diaz-Brito [16], Maria J. Galindo [17], Sergio Ferra [18], Aroa Villoslada [19], Juan E. Losa [20], Francisco J. Fanjul [21], Javier Perez-Stachowski [22], Joaquim Peraire [23], Joaquin Portilla [24], Sara de la Fuente [25], Carlos Dueñas [26], Maria J. Vazquez [27], Silvana Di Gregorio [28], Eduardo Manzanares [29], Pedro Gil [29], Marta de Miguel [29], Jose L. Blanco [30], Pablo Ryan [31], Belen Alejos [32], Esteban Martinez [30], for Paso-Doble (GeSIDA 11720) Randomized Trial Team.

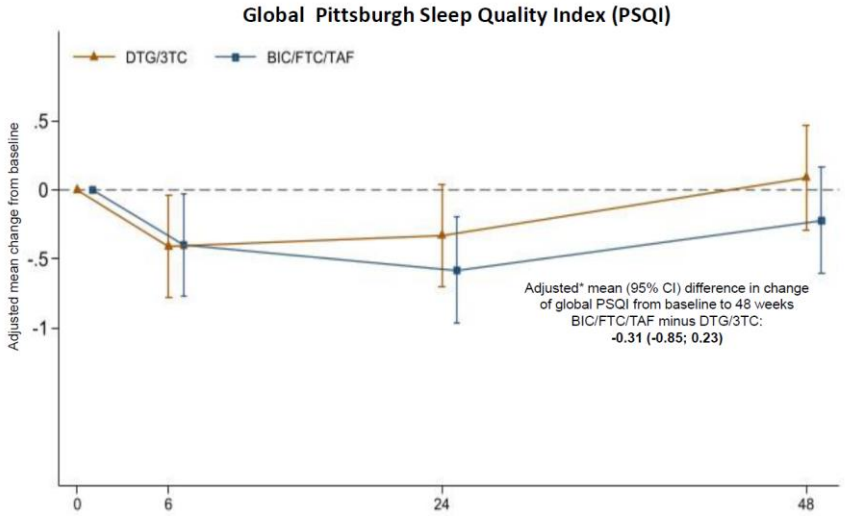
[1] Hospital Universitario de la Princesa, Madrid, Spain; [2] Hospital General Universitario, Elche, Spain; [3] Hospital Clínico Universitario Lozano Blesa, Zaragoza, Spain; [4] Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; [5] Hospital Universitari Vall d'Hebron, Barcelona, Spain; [6] Hospital del Mar, Barcelona, Spain; [7] Hospital Reina Sofía, Murcia, Spain; [8] Hospital Morales Meseguer, Murcia, Spain; [9] Hospital Universitari Germans Trias i Pujol, Badalona, Spain; [10] Hospital Universitario Virgen de Valme, Sevilla, Spain; [11] Hospital Universitario de Bellvitge, L'Hospitalet de Llobregat, Spain; [12] Hospital Universitario La Paz, Madrid, Spain; [13] Hospital Marina Baixa, Villajoyosa, Spain; [14] Hospital Universitario, Guadalajara, Spain; [15] Hospital Juan Ramon Jimenez, Huelva, Spain; [16] Parc Sanitari Sant Joan de Deu, Sant Boi de Llobregat, Spain; [17] Hospital Clínico Universitario, Valencia, Spain; [18] Hospital Universitario Torrecardenas, Almeria, Spain; [19] Hospital Universitario Son Llatzer, Palma de Mallorca, Spain; [20] Hospital Universitario Fundacion Alcorcon, Alcorcon, Spain; [21] Hospital Universitario Son Espases, Palma de Mallorca, Spain; [22] Hospital Costa del Sol, Marbella, Spain; [23] Hospital Universitari Joan XXIII, Tarragona, Spain; [24] Hospital General Universitario Dr. Balmis, Alicante, Spain; [25] Hospital Universitario Puerta de Hierro-Majadahonda, Majadahonda, Spain; [26] Hospital Clínico Universitario, Valladolid, Spain; [27] ViiV Healthcare, Tres Cantos, Spain; [28] CP Endocrinologia i Nutrició S.L., Barcelona, Spain; [29] Fundación SEIMC-GeSIDA, Madrid, Spain; [30] Hospital Clínic & University of Barcelona, Infectious Diseases Unit, Barcelona, Spain; [31] Hospital Universitario Infanta Leonor, Madrid, Spain; [32] Independent researcher, Madrid, Spain.

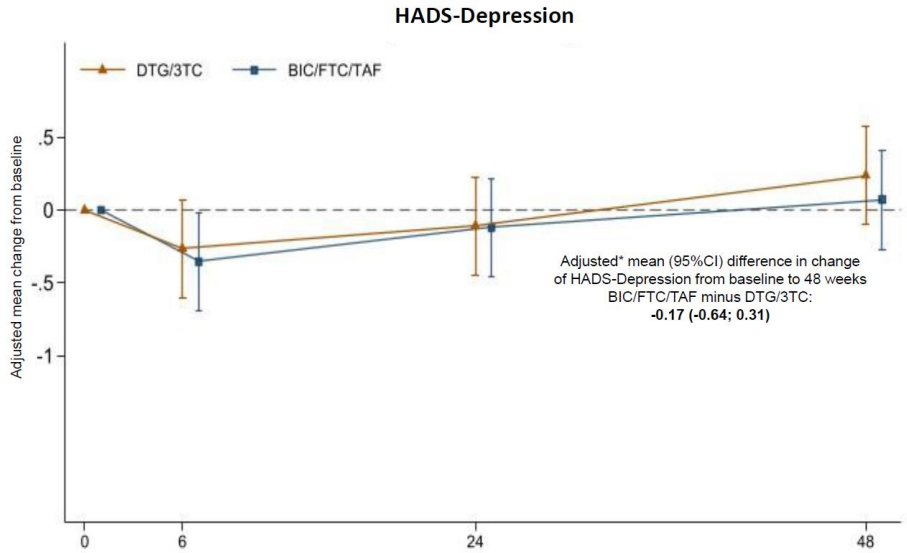
Results: Patient Reported Outcomes (PROMs) at baseline

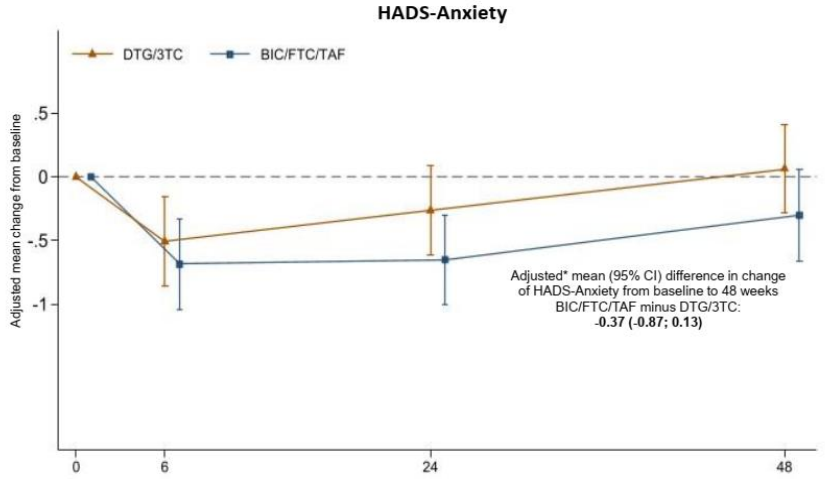
	DTG/3TC (n=277)	BIC/FTC/TAF (n=276)	P-value
Global Pittsburgh Sleep Quality Index (PSQI)			
Mean (standard deviation)	6.3 (3.5)	5.5 (3.5)	0.011
Proportions (95%CI) of scores >5 (poor sleep)	61.9 (55.3-68.2)	55.1 (48.4-61.7)	0.141
HADS-Anxiety			
Mean (standard deviation)	5.4 (3.7)	5.3 (3.9)	0.695
Proportions (95%CI) of scores >8 (mild anxiety)	24.2 (19.2-29.7)	24.4 (19.4-29.9)	0.959
Proportions (95%CI) of scores >11 (moderate anxiety)	9.9 (6.6-14.1)	9.1 (6.0-13.1)	0.750
HADS-Depression			
Mean (standard deviation)	3.2 (3.1)	3.6 (3.6)	0.173
Proportions (95%CI) of scores >8 (mild depression)	9.6 (6.4-13.7)	12.4 (8.7-16.8)	0.301
Proportions (95%CI) of scores >11 (moderate depression)	3.0 (1.3-5.7)	6.9 (4.2-10.6)	0.033
HIV Symptoms Index (HSI)			
Mean total scores (standard deviation)	13.9 (11.5)	12.5 (11.5)	0.158

D'après le poster de Martinez et al. Changes in patient-reported neuropsychological outcomes in virologically suppressed persons with HIV switching to DTG/3TC or BIC/FTC/TAF: a substudy of the PASO-DOBLE randomized clinical trial. P043. HIV Glasgow 2024

Results: Mean adjusted* changes from baseline in PSQI, HospitalAnxiety and Depression Scale (HADS), and HSI tools







D'après le poster de Martinez et al. Changes in patient-reported neuropsychological outcomes in virologically suppressed persons with HIV switching to DTG/3TC or BIC/FTC/TAF: a substudy of the PASO-DOBLE randomized clinical trial. P043. HIV Glasgow 2024

Conclusions

- Poor sleep quality and anxiety were very common in this clinically stable cohort
- There was an initial transient improvement in patient-reported Neuropsychological outcomes after switching to DTG/3TC or BIC/FTC/TAF, but at 48 weeks there were no differences within or between arms

D'après le poster de Martinez et al. Changes in patient-reported neuropsychological outcomes in virologically suppressed persons with HIV switching to DTG/3TC or BIC/FTC/TAF: a substudy of the PASO-DOBLE randomized clinical trial. P043. HIV Glasgow 2024

Mental health in people with HIV (PWH): Patient-reported outcomes in the DUALIS study

P325

Wolf E*[1], Balogh A[1], Voit F[2], Laufenberg J[3], Boesecke C[3], Koegl C[1], Spinner C[2], Dinkel A[4,5]

[1]MUC Research, Munich, [2]TUM School of Medicine and Health, Department of Clinical Medicine – Clinical Department for Internal Medicine II, University Medical Center, Technical University of Munich, Munich, [3]University Hospital Bonn, Department of Internal Medicine I, Bonn, [4]Münchner Studienzentrum (MSZ), Munich, [5]TUM School of Medicine and Health, Department of Clinical Medicine – Clinical Department for Psychosomatic Medicine and Psychotherapy, University Medical Center, Technical University of Munich, Munich, all Germany.

Results

HADS/D scores at time of inclusion (baseline)

- At baseline, the median HADS/D score (IQR) was 3 (1-6)
- The prevalence of at least moderate or of severe depression using HADS/D scores of ≥8 and ≥11, was 17% (n=44/259) and 5% (14/259), respectively
- 15% of PWH (38/255) received psychotherapy or psychotropic treatment/pharmacotherapy, 36% of those with HADS/D≥8 (15/42), 11% of those with HADS/D<8 (23/213)
- The baseline prevalence of anxiety using an HADS/A score ≥8 [≥11] was 24% (n=63/259) [9% (n=23/259)]
- Anxiety was highly correlated with depression: in those with HADS/D≥8, median HADS/A score (IQR) was 10 (7-12) (in comparison to 4 (2-6) in those with HADS/D<8)
- Median (IQR) score for MOS-HIV mental health* was 80 (60-88)

Table 2. HADS/D and HADS/A scores at baseline and at week 48

	2DR (N=128)	3DR (N=131)
HADS/D scores at baseline; median (IQR)	3 (1-6)	2 (1-5)
HADS/D scores at week 48; median (IQR)	3 (1-6)	2 (0-6)
HADS/D scores ≥8 at week 48; n/N (%)	23/120 (19)	20/121 (17)
Change in HADS/D scores at week 48 from baseline; median (IQR)	0 (-2-+1)	0 (-1-+2)
HADS/A scores at baseline; median (IQR)	6 (3-8)	4 (2-7)
HADS/A scores at week 48; median (IQR)	5 (2-9)	4 (2-7)
HADS/A scores ≥8 at week 48; n/N (%)	36/118 (31)	25/121 (21)
Change in HADS/A scores at week 48 from baseline; median (IQR)	0 (-2-+1)	0 (-2-+2)

*Overall range (0-100); higher scores representing better outcomes

D'après le poster de Wolf et al. Mental health in people with HIV (PWH): Patient-reported outcomes in the DUALIS study. P325. HIV Glasgow 2024

Conclusions

- In the DUALIS study, the prevalence of elevated baseline HADS/D and HADS/A scores indicating anxiety and depression were 17% and 24%, respectively
- HADS scores remained largely unchanged over 48 weeks while on either continuous darunavir/ritonavir+2NRTI-based ART or on darunavir / ritonavir + dolutegravir
- In this selected group of people with HIV, only higher age and female gender were significantly associated with higher depression scores. Disease related and sociodemographic variables did not show a significant association
- Patient-reported outcome measures may help identifying people with HIV in need for therapeutic intervention

D'après le poster de Wolf et al. Mental health in people with HIV (PWH): Patient-reported outcomes in the DUALIS study. P325. HIV Glasgow 2024

Risk of Hypertension in Treatment-Naïve People With HIV in the US Receiving INSTI Versus NNRTI, or TAF– Versus Non-TAF–Based Regimens: Pooled Analysis of Blood Pressure Data From Five Clinical Trials

P283

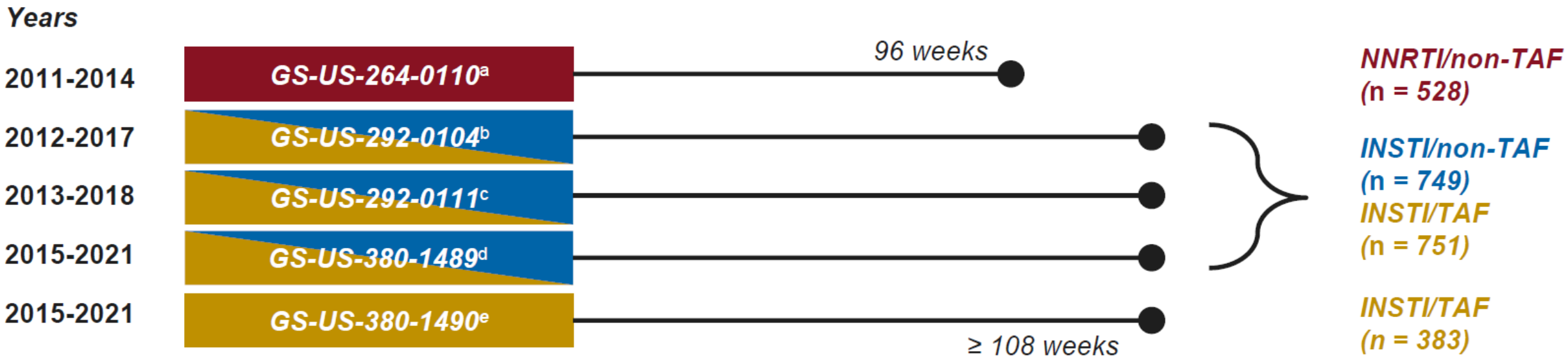
NCT01309243, NCT01780506, NCT01797445, NCT02607930, NCT02607956

Priscilla Y Hsue[1], Laura Waters[2], Chloe Orkin[3], Juan Manuel Tiraboschi[4], Anchalee Avihingsanon[5], Andrea Marongiu[6], Andrew Whiteman[7], Yuan Tian[7], Carrie M Nielson[7], Keith Aizen[7], Cal Cohen[7], Jason T Hindman[7], Jürgen K Rockstroh[8]

[1]University of California San Francisco, San Francisco, CA, USA; [2]Mortimer Market Centre, Central and North West London NHS Foundation Trust, London, UK; [3]Blizard Institute, Queen Mary University, London, UK; [4]Bellvitge University Hospital, Barcelona, Spain; [5]HIV-NAT, Thai Red Cross AIDS Research Centre, Bangkok, Thailand; [6]Gilead Sciences Ltd, Stockley Park, Uxbridge, UK; [7]Gilead Sciences, Inc., Foster City, CA, USA; [8]University of Bonn, Bonn, Germany

Study Design

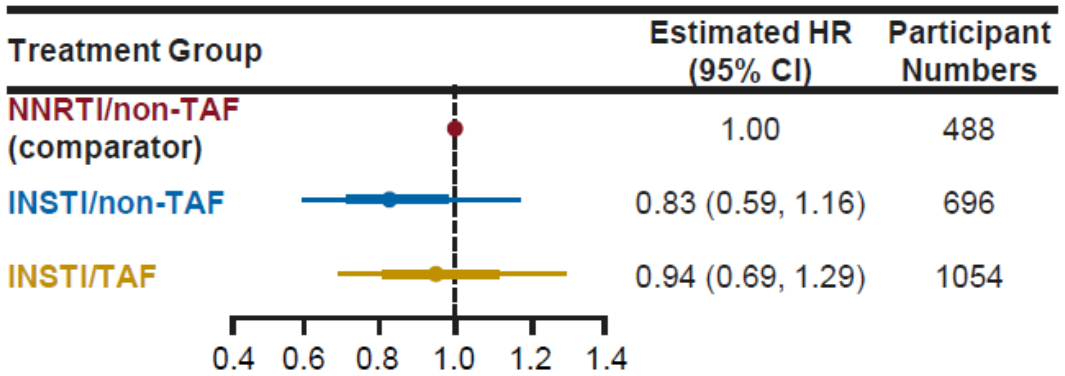
- In this post hoc analysis, US participants' data were pooled from five randomized, double-blind, Phase 3 studies including adults with HIV receiving NNRTI/non-TAF, INSTI/non-TAF, or INSTI/TAF regimens as first-line ART[6-10]
- Participant data were grouped by ART drug class (INSTI vs NNRTI) and by regimen within the same nucleoside/nucleotide reverse transcriptase inhibitor class (TAF vs non-TAF)



aNCT01309243, treatment groups: RPV/F/TDF STR vs EFV/F/TDF.6 bNCT01780506, treatment groups: EVG/COBI/F/TAF (STR) vs EVG/COBI/F/TDF (STR).7 cNCT01797445, treatment groups: EVG/COBI/F/TAF (STR) vs EVG/COBI/F/TDF (STR).8 dNCT02607930, treatment groups: B/F/TAF (STR) vs ABC/DTG/3TC (STR).9 eNCT02607956, treatment groups: B/F/TAF (STR) vs DTG + F/TAF multi-tablet regimen.10 3TC, lamivudine; ABC, abacavir; B, bictegravir; COBI, cobicistat; DTG, dolutegravir; EFV, efavirenz; EVG, elvitegravir; F, emtricitabine; INSTI, integrase strand transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; RPV, rilpivirine; STR, single tablet regimen; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

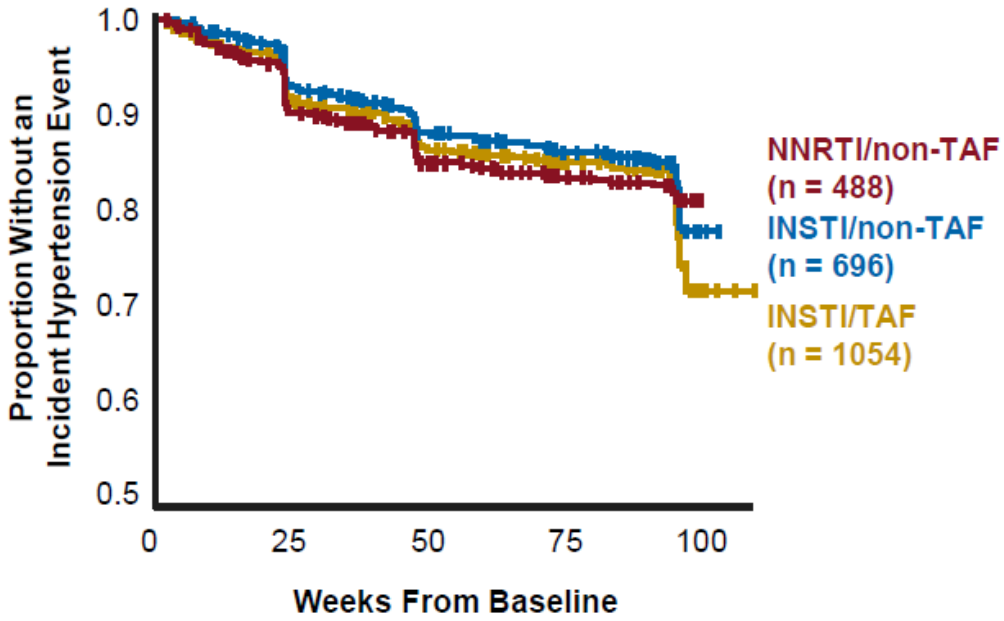
D'après le poster de Hsue et al. Risk of Hypertension in Treatment-Naïve People With HIV in the US Receiving INSTI Versus NNRTI, or TAF– Versus Non-TAF–Based Regimens: Pooled Analysis of Blood Pressure Data From Five Clinical Trials. P283. HIV Glasgow 2024

Incident Hypertension Events in Participants With No Evidence of Hypertension at Baseline (N = 2238)



Composite Hypertension Events Measured During Follow-Up at Week 24, 48, or 96	
Total events, n (%)	425 (19)
Consecutive blood pressure records indicating Stage ≥ 2 hypertension	171 (8)
Initiation of antihypertensive medication	169 (8)
Hypertension-related adverse event	85 (4)

Hypertension-Free Participants, by Treatment



Scan the QR code for antihypertensive medication initiations by group

QR CODE

Marginal proportions/HRs in the Forest plot above were adjusted for baseline covariates, including age, alanine aminotransferase, BMI, eGFR, sex at birth, race, and systolic and diastolic blood pressure. Thin lines indicate approximate 95% CIs, thick lines indicate SEs. Participants with hypertension at baseline (existing diagnoses and/or receiving antihypertensive medication) were excluded (n = 173).
BMI, body mass index; eGFR, estimated glomerular filtration rate; HR, hazard ratio; INSTI, integrase strand transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; TAF, tenofovir alafenamide.

The primary analysis showed similar or slightly lower odds of higher hypertension stage in the INSTI groups versus the NNRTI/non-TAF group; the secondary analyses support these findings

D'après le poster de Hsue et al. Risk of Hypertension in Treatment-Naïve People With HIV in the US Receiving INSTI Versus NNRTI, or TAF– Versus Non-TAF–Based Regimens: Pooled Analysis of Blood Pressure Data From Five Clinical Trials. P283. HIV Glasgow 2024

Conclusions

- Baseline hypertension (Grade: Stage ≥ 1) was present in ~50% of this sample of relatively young people with HIV taking first-line ART, yet few were taking antihypertensive medication
- INSTI/TAF and INSTI/non-TAF treatments showed similar or slightly lower odds of hypertension than NNRTI/non-TAF treatment
- Blood pressure–related events (initiation of antihypertensives, adverse events, and Stage ≥ 2 hypertension) occurred in 19% of participants over a relatively short time
- This analysis highlights the need for careful monitoring and appropriate treatment of hypertension in this population, regardless of ART choice

D'après le poster de Hsue et al. Risk of Hypertension in Treatment-Naïve People With HIV in the US Receiving INSTI Versus NNRTI, or TAF– Versus Non-TAF–Based Regimens: Pooled Analysis of Blood Pressure Data From Five Clinical Trials. P283. HIV Glasgow 2024

P383

Preliminary results of a pilot study to evaluate the usefulness of using patient-reported outcomes (PROs) in the follow-up of patients living with HIV

Sara De la Fuente Moral[1], María Pilar Corrales Rodríguez[2], Ana Belén Hernandez López[3], Carlos Folguera Olías[4], Belén Menchén Viso[4], Miriam Redondo[5], Victoria Ayala Vargas[6], María Sainz Guerra[7], Alberto Díaz de Santiago[1]

1. HIV Unit, Puerta de Hierro University Hospital, Madrid. 2. Nursing Department, Puerta de Hierro University Hospital, Madrid. 3. Nursing Department, Puerta de Hierro University Hospital, Madrid. 4. Hospital Pharmacy Department, Puerta de Hierro University Hospital, Madrid. 5. HOPES (HOH HEALTH SL), Madrid. 6. Government Affairs, Gilead Sciences Spain. 7. Medical department, Gilead Science Spain.

Methods

HOH-HIV study, prospective and randomized, of 1 year duration. For this purpose, the hospital has installed a plateform for the collection and visualization of data and PROs:

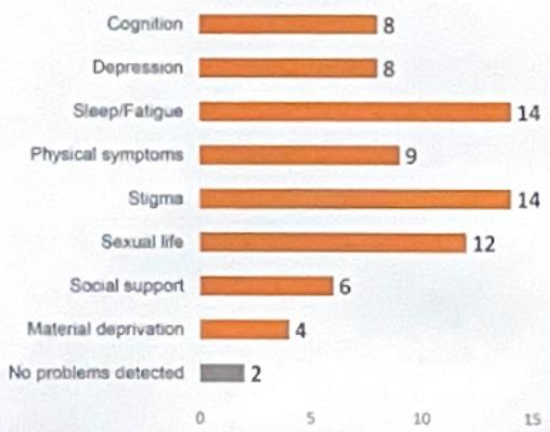
- **Active group** (N = 50): invited to respond quarterly, in a remote way, to the quality of life questionnaires of the Clinic Screening Tool (CST) and WHO-QoL-bref. If the score exceeds the established thresholds, a nurse contacts the patient and advises his doctor, if necessary

- **Control group** (N = 50): follow-up according to usual clinical practice

Results

- Detection of health/quality of life problems in the **active group**:
  - CST/WHO-QoL-bref response rates: **40%** (20/50).
    - The response rate has been affected by technical problems, loss of interest and stigma compared with other patient populations.
  - Quality of life of patients measured by the WHO-QoL:
    - 80% of the patients living with HIV who completed at least one WHO-QoL questionnaire reported good perceived quality of life.

- Problems detected according to the CST in 18/20 (**91.5%**) patients:
  - Some of them were not detected in the consultation, especially in the areas of cognition, sexuality and stigma.
  - Some differences were detected based on sex.



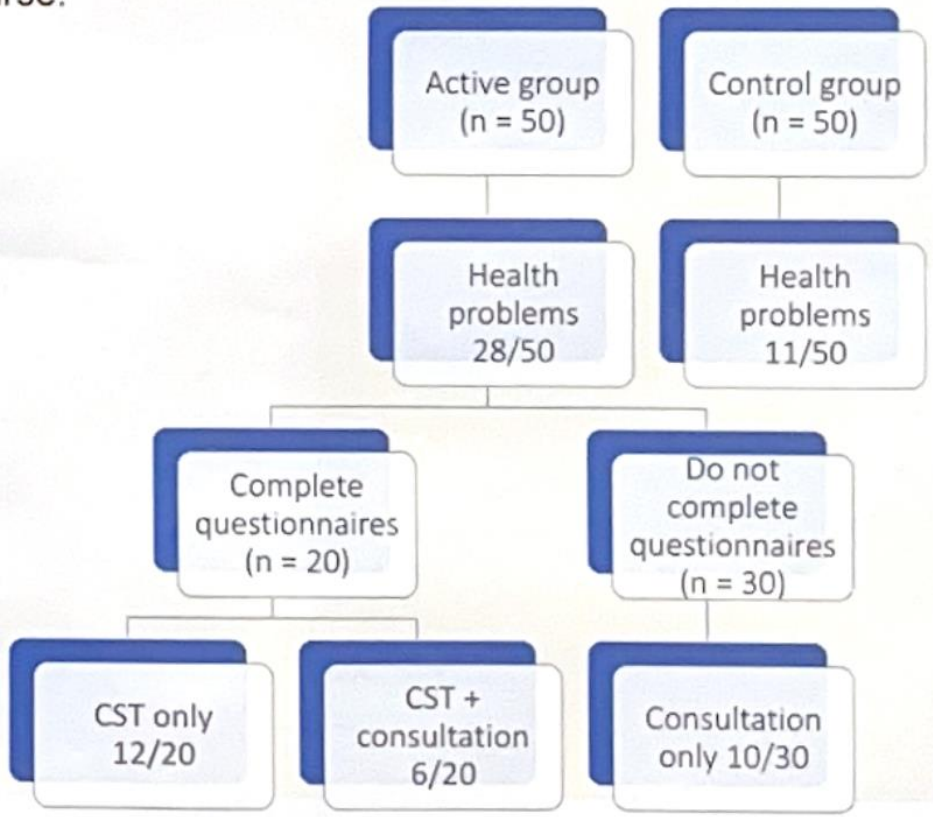
	Males (%)	Women (%)
Cognition	7/15 (46.66)	1/3 (33.33)
Depression	7/15 (46.66)	1/3 (33.33)
Sleep/Fatigue	12/15 (80)	2/3 (66.66)
Physical symptoms	7/15 (46.66)	2/3 (66.66)
Sexual life	10/15 (66.66)	2/3 (66.67)
Stigma	12/15 (80)	2/3 (66.66)
Social support	6/15 (40)	0
Material deprivation	3/15 (20)	1/3 (33.33)

- Problems detected during **face-to-face consultations**:

16/50 patients commented on some problem related to HIV, of whom 6 had already reported it in the CST and 10 only in consultation.

Results

- Detection of problems in the **active group vs. the control group:**
  - The detection rate of health or quality of life problems in the active group (28/50 = **56%**) was significantly higher (p = 0.044) than that in the control group (11/50 = **22%**), which could be explained by the greater self-perception due to the questionnaires and the intervention of the nurse.



SOUS L'ÉGIDE DE VIH ACTU

ÉDITÉ PAR KEPHREN PUBLISHING

AVEC LE SOUTIEN DE GILEAD

Soirée inédite

Les Francophones de Glasgow

MARDI 12 NOVEMBRE 2024

à partir de 18h00

CROWNE PLAZA GLASGOW

Congress Road - GLASGOW, G3 8QT, UK