

Salvage ART regimens based on a combination of an integrase inhibitor and doravirine in heavily antiretroviral treated people living with HIV

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Background

- Due to particular epidemiological aspects and poor adherence in Romanian people living with HIV (PLWH), salvage ART regimens were more frequently used.
- The aim of the study was to assess epidemiological aspects and outcomes in PLWH under salvage ART regimens based on a combination of a non-nucleoside reverse transcriptase inhibitor (DOR) and an integrase inhibitor – Dolutegravir (DTG) or Bictegravir (BIC).

Methods

- Prospective study on PLWH in active care during between January and December 2023 at “Victor Babes” HIV Regional Center Bucharest, with ART containing a combination of DOR with either DTG or BIC.
- ARN-HIV not detected (ND) was defined as viral load (VL) < 40 copies/mL.
- Statistical comparisons were performed using Mann Whitney test for quantitative variables and Chi-square test for qualitative ones (SPSS vs 20.1).

Results

Socio-demographic characteristics of PLWH on salvage ART regimens

Characteristics	Total n=69
Male sex	n (%) 40 (57.9)
Age (years)	median (IQR) 36 (35-49)
Mode of HIV acquisition	
parenteral mode during childhood (PM)	44 (63.7)
heterosexual contact (HSX)	18 (26.0)
injecting drug use (PWID)	3 (4.3)
men having sex with men (MSM)	1 (1.4)
vertical transmission	3 (4.3)

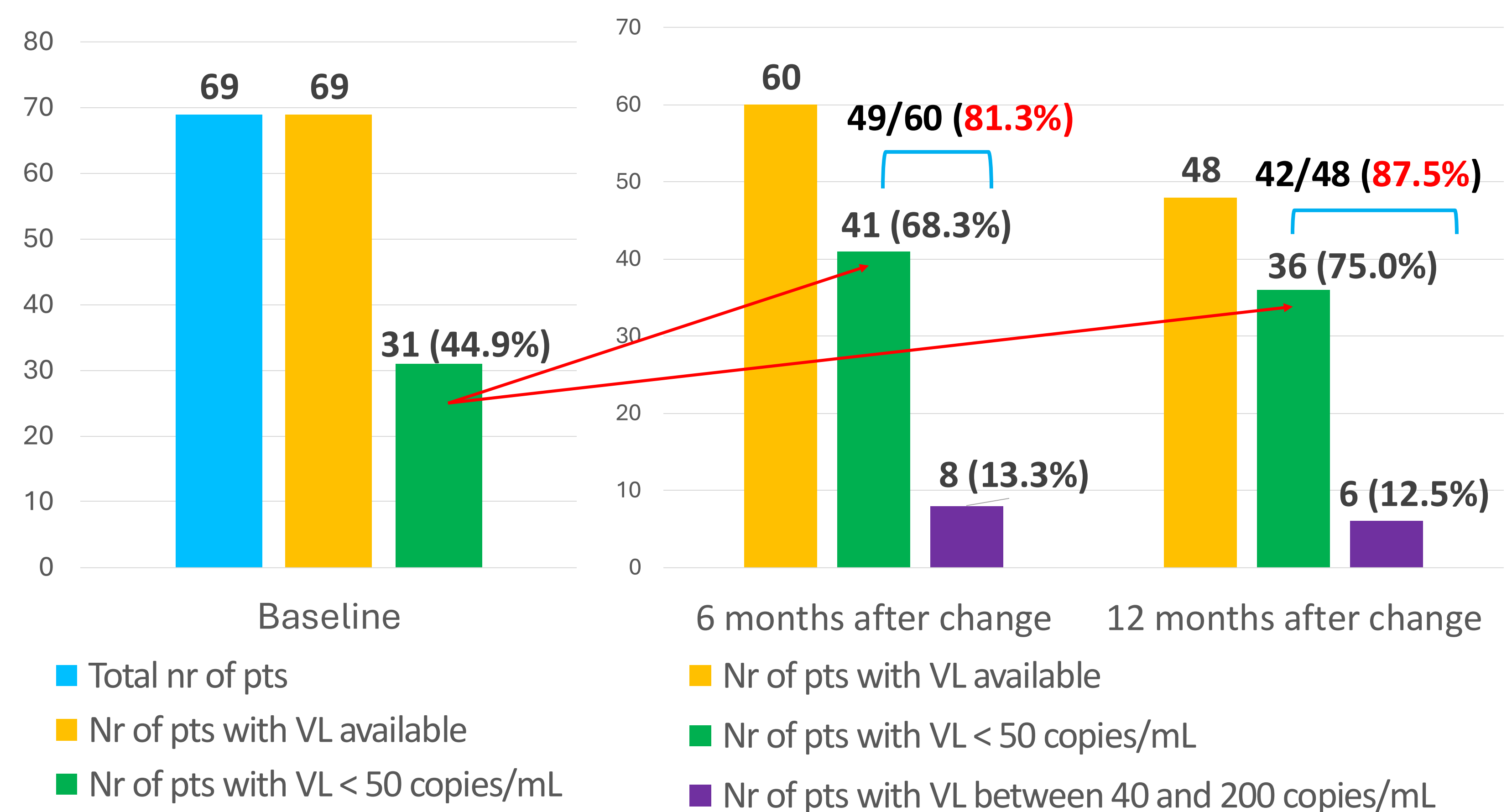
ART history, immunological and virological aspects in PLWH on salvage ART regimens

Characteristics	Total n=69
Duration on ART before change (years)	median (IQR) 21.5 (15.75-24)
Nadir CD4 cell count/ μ L	median (IQR) 37 (15-124)
HIV-RNA (\log_{10} copies/mL) at diagnosis	median (IQR) 5.24 (4.71-5.69)
CD4 cell count/ μ L at change	median (IQR) 296 (151-640)
HIV-RNA at change - ND	n (%) 31 (45.5)
No. of previous ART regimens	n (%) 7 (5-8.25)
Duration under INSTI (years)	median (IQR) 6 (3-10)
Duration under PIs (years)	median (IQR) 15 (8-20)
Duration under NNRTIs (years)	median (IQR) 4 (2-10)

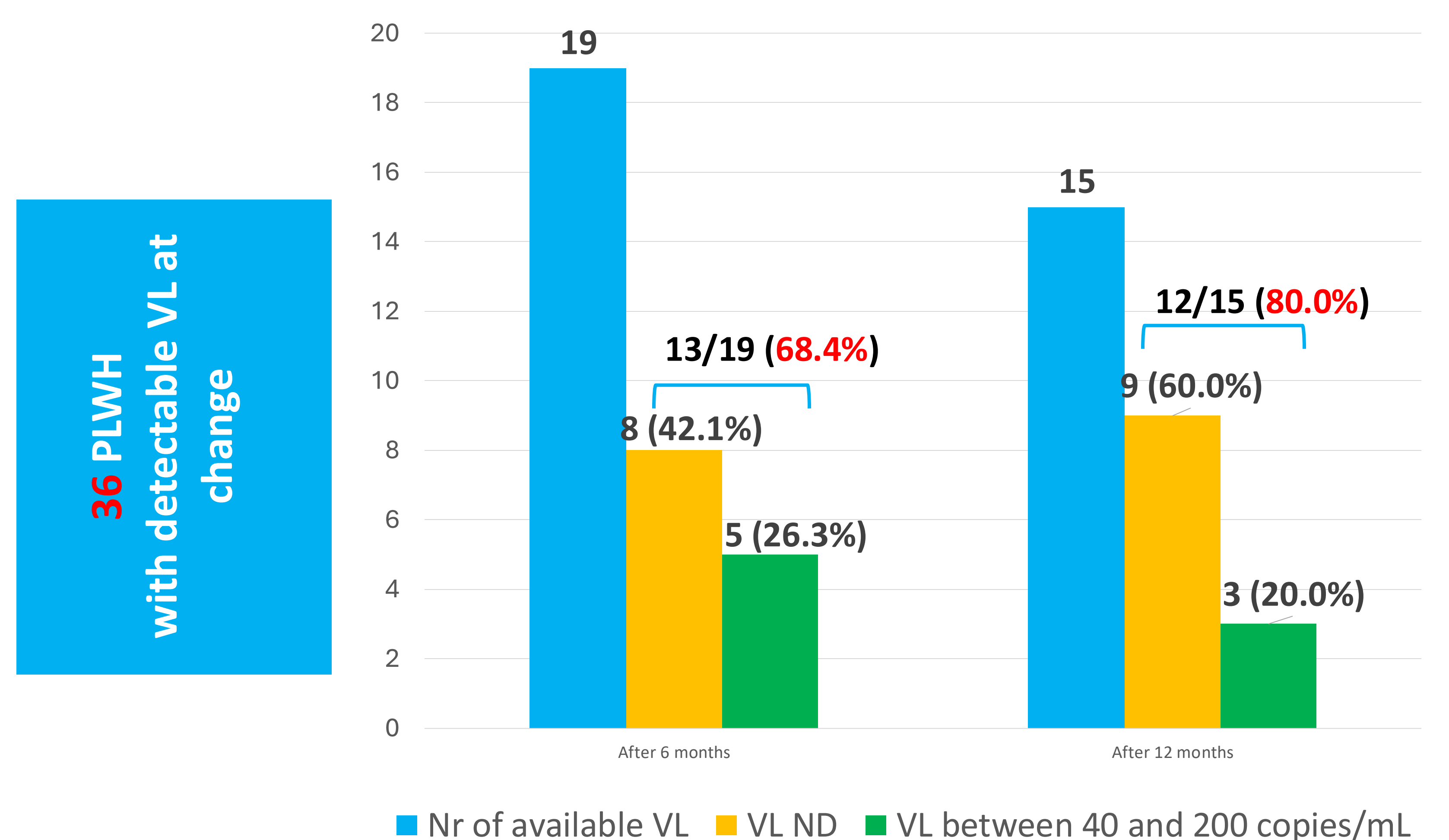
Characteristics of PLWH on salvage ART regimens – comparison based on modes of HIV acquisition

Characteristics	PM N=44	HSX N=18	p value
Male sex	n (%) 24 (54.5)	9 (50.0)	0.481
Age (years)	median (IQR) 35.5 (35-36)	49 (36.75-59.5)	0.011
Duration on ART before change	median (IQR) 23.5 (21-25)	11 (6.75-16.5)	<0.0001
Nadir CD4 cell count/ μ L	median (IQR) 80 (12.5-113)	49.5 (18.5-135.75)	0.569
HIV-RNA (\log_{10} copies/mL) at diagnosis	median (IQR) 5.23 (4.90 – 5.69)	5.27 (4.70-5.56)	0.964
CD4 cell count at ART change/ μ L	median (IQR) 309.5 (175 – 684.25)	331.5 (106.75 – 572.5)	0.424
HIV-RNA at change - ND	n (%) 21 (47.7)	9 (50.0)	0.546
Nr of previous ART regimens	n (%) 7 (5.75 – 9)	5 (4-6)	<0.0001
Duration on INSTI (years)	median (IQR) 7 (4-12)	4.25 (2.25-6)	0.001
Duration on PIs (years)	median (IQR) 17 (10-21.5)	6 (2-10)	0.024
Duration on NNRTIs (years)	median (IQR) 6 (3-10)	3 (1-8.75)	<0.0001

Virological suppression rates after initiation of salvage ART regimens



Dynamic of ARN-HIV in plasma after initiation of salvage ART regimens in PLWH with adherence problems



PLWH on salvage ART regimens

69 PLWH on salvage ART regimens

35 (50.7%)
BIC/FTC/TAF + DOR

24 (35.2%)
3TC/TDF/DOR + DTG

10 (14.7%)
3TC/DTG + DOR

Most common reasons for ART change:

• simplification (32)

• virological failure (37)

Characteristics of PLWH on salvage ART regimens – comparison based on ART regimen

Characteristics		BIC/FTC/TAF + DOR N=35	3TC/TDF/DOR + DTG N=24	3TC/DTG + DOR N=10	p value
Nadir CD4 cell count/ μ L	median (IQR)	75 (21-135)	44.5 (10-115.5)	73.5 (22.7-115.5)	0.610
HIV-RNA at diagnosis \log_{10} copies/mL	median (IQR)	5.08 (4.08-5.69)	5.16 (4.81-5.44)	5.76 (5.45 - 5.96)	0.187
CD4 cell count at change/ μ L	median (IQR)	305 (163-637)	220 (101-452.5)	755 (381.5-1035.5)	0.049
HIV-RNA at change - ND	n (%)	16 (47.0)	8 (33.3)	7 (70.0)	0.143
Nr of previous ART regimens	n (%)	7 (5-8.75)	7 (4.5-8)	5.5 (5-8.5)	0.874
Duration under INSTI (years)	median (IQR)	4 (2-10)	6 (4.25-7.75)	8 (5-14)	0.096
Duration under PIs (years)	median (IQR)	16.5 (10-21.25)	13.5 (7.75-17.75)	12 (5.5-17.5)	0.339
Duration under NNRTIs (years)	median (IQR)	4 (2-10.5)	3 (1-9)	6.5 (3-11)	0.529

Conclusions

- The number of PLWH changed to salvage ARV regimens significantly increased during last year, especially among PM with heavy ART history. All salvage ART regimens were effective in PLWH adherent to ART.
- More data is needed to prove if STRs with high genetic barrier are an efficient and durable option in PLWH with extensive treatment history or if regimens with DTG/BIC and DOR can also be effective in these group.