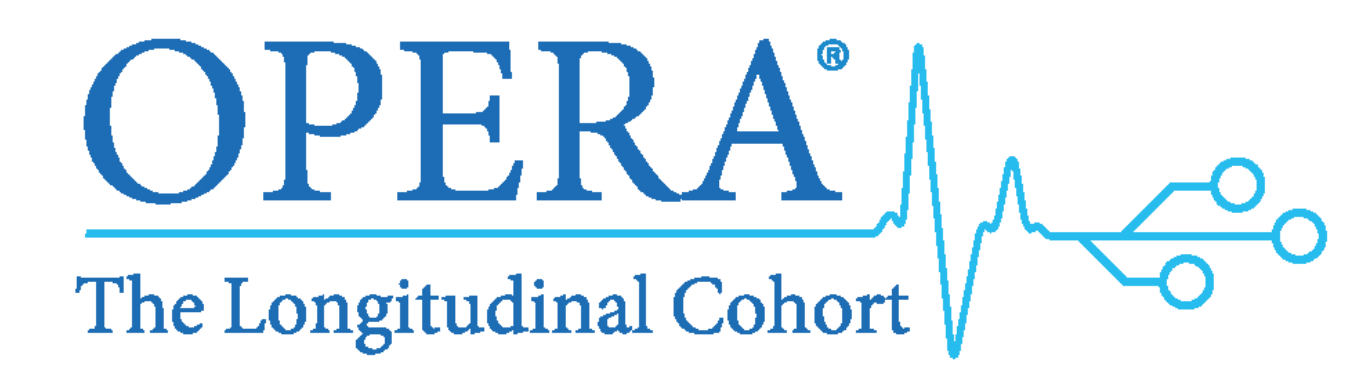


# Characterizations of weight gain following antiretroviral regimen initiation in treatment-naïve individuals living with HIV

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## Background

- Obesity and body mass index (BMI) have been rising among people living with HIV (PLWH) over time<sup>1</sup>
- Recent reports of weight gain associated with ART
  - With integrase inhibitors (INSTI)<sup>2</sup>
  - With dolutegravir (DTG)<sup>3,4</sup>
  - With TAF<sup>4</sup>

## Objective

To describe weight gain continuously and at various thresholds (≥3 kg, ≥5 kg, or ≥5% increase from baseline) in ART-naïve PLWH initiating common core agents

## Methods

### Study population

- OPERA cohort
  - Prospectively captured, routine clinical data from electronic health records in the US (84 clinics, 17 states, 1 US territory)
  - ~8% of PLWH in care in the US
- Inclusion criteria
  - ART-naïve PLWH ≥18 years (not pregnant or transgender)
  - Initiating ART for the first time between 01AUG2013 and 31DEC2017 with 1 core agent: dolutegravir (DTG), elvitegravir/cobicistat (EVG/c), raltegravir (RAL), rilpivirine (RPV), or boosted darunavir (bDRV)
  - ≥ 1 baseline viral load measurement
  - ≥ 1 weight measurement ≤ 3 months before ART initiation
  - ≥ 1 weight measurement during follow-up
- Observation period: from regimen initiation until: (1) core agent discontinuation/addition, (2) ≥ 12 months without contact, (3) pregnancy, (4) death, or (5) study end (31DEC2018)

### Analyses

- Changes in weight from ART initiation assessed at 6, 12, and 24 months, ± 3 months
  - Mean change in weight or BMI
  - Changes in BMI category: Underweight (<18.5), Normal (18.5–24.9), Overweight (25.0–29.9), Obese (≥30)
  - Pronounced weight gain: ≥3 kg, ≥5 kg, ≥5%

## Results

Table 1. Baseline demographic and clinical characteristics (N=6,246), n (%)

	DTG n=2118	EVG/c n=2665	RAL n=116	RPV n=757	bDRV n=590
Age ≥50 years	237 (11.2)	287 (10.8)	40 (34.5)*	57 (7.5)*	81 (13.7)*
Female	245 (11.6)	285 (10.7)	36 (31.0)*	131 (17.3)*	99 (16.8)*
Black non-Hispanic	881 (41.6)	1225 (46.0)*	60 (51.7)*	406 (53.6)*	321 (54.4)*
Hypertension	240 (11.3)	300 (11.3)	28 (24.1)*	115 (15.2)*	82 (13.9)
Endocrine disorders <sup>a</sup>	239 (11.3)	258 (9.7)	22 (19.0)*	44 (7.5)*	92 (12.2)
TAF use	247 (11.7)	1167 (43.8)*	7 (5.7)*	144 (19.0)*	158 (26.8)*
Medication associated with weight gain <sup>b</sup>	228 (10.8)	245 (9.2)	26 (22.4)*	90 (11.9)	87 (14.7)*
HIV RNA ≥100,000 copies/mL	692 (32.7)	853 (32.0)	25 (21.6)*	36 (4.8)*	239 (40.5)*
CD4 cell count ≤200 cells/μL	455 (21.5)	581 (21.8)	37 (31.9)*	53 (7.0)*	250 (42.4)*

\* p-value <0.05 for the comparison with DTG  
<sup>a</sup> Type 1 Diabetes Mellitus, Type 2 Diabetes Mellitus, Hyperlipidemia, Hypothyroidism, or Thyroiditis  
<sup>b</sup> Select antipsychotics/mood stabilizer, antidepressants, antihyperglycemics, antihypertensives, corticosteroids, hormones, anticonvulsants, antihistamines

Table 2. Mean unadjusted change in BMI from baseline, kg/m<sup>2</sup> (95 % CI)

	DTG	EVG/c	RAL	RPV	bDRV
6 months (n=5,751)	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)	0.4 (0.1, 0.7)	0.5 (0.4, 0.6)	0.9 (0.7, 1.1)
12 months (n=4,606)	1.2 (1.1, 1.3)	1.2 (1.1, 1.3)	0.9 (0.3, 1.5)	0.5 (0.2, 0.8)	1.6 (1.3, 1.9)
24 months (n=2,427)	1.7 (1.5, 1.9)	1.4 (1.2, 1.6)	0.6 (-0.5, 1.7)	1.0 (0.6, 1.4)	1.8 (1.2, 2.4)

Figure 2. Mean unadjusted change in weight from baseline, kg (95% CI)

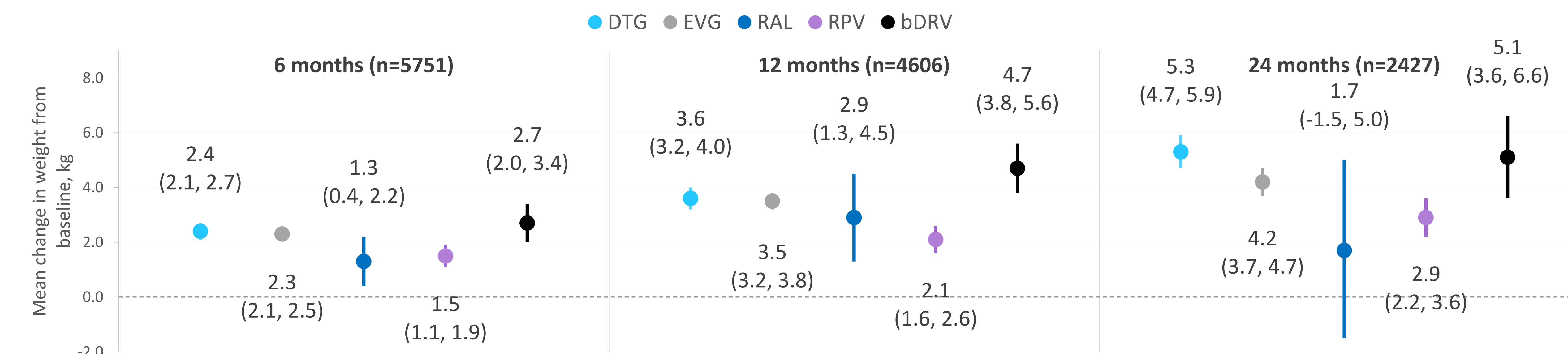


Figure 3. Changes in BMI category at 12 months (among PLWH with weight measurement at 9-15 months)

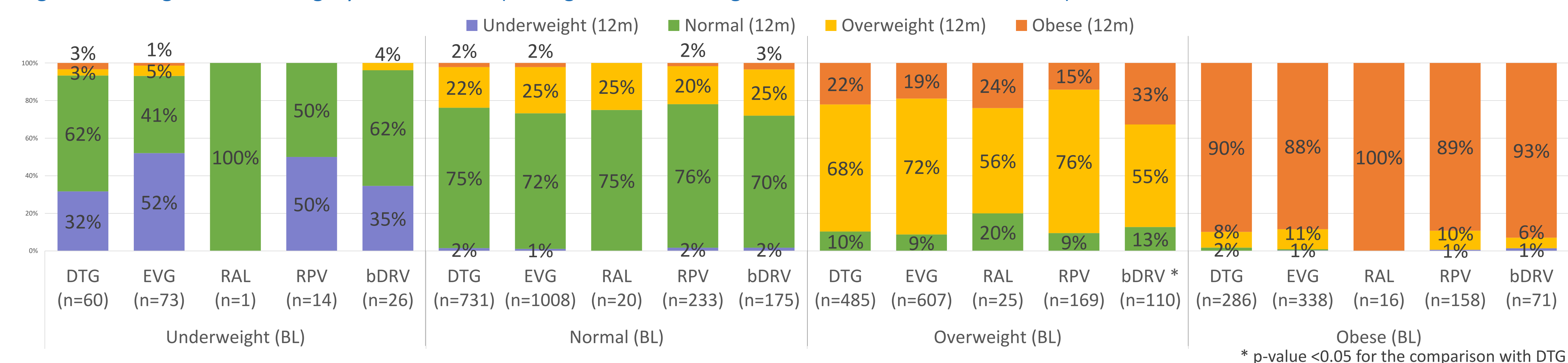
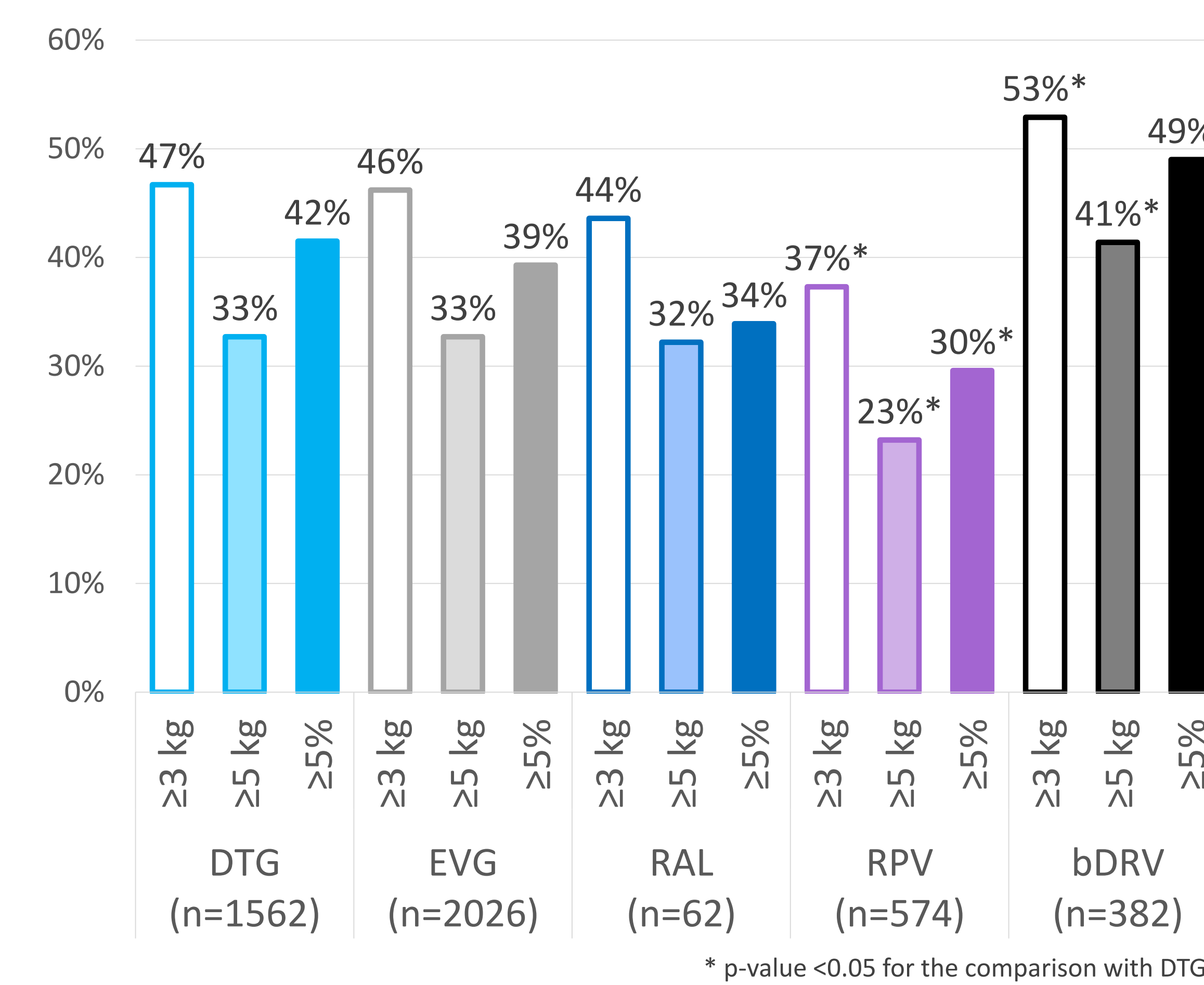


Figure 1. Pronounced weight gain at 12 months (among PLWH with weight measurement at 9-15 months)



## Discussion

- Substantial proportion of PLWH experiencing weight gain across groups over up to 24 months of follow-up (Fig 1,3)
- The proportion of PLWH with pronounced weight gain varied across thresholds and group (Fig 1)
- Large proportion of PLWH with pronounced weight gain:
  - 30-49% gained ≥5% of their baseline body weight (Fig 1)
  - 15-33% of PLWH with normal or overweight baseline BMI gained enough weight to increase by ≥1 BMI category at 12 months (Fig 3)
- PLWH initiating bDRV experienced the greatest weight gain (Fig 1,2); highest proportion of high viremia and low CD4 cell counts (Table 1)
- PLWH initiating RPV experienced the least weight gain (Fig 1,2); lowest proportion of high viremia and low CD4 cell counts (Table 1)
- Limitation: no adjustment for baseline differences between groups for weight gain related to restoration of health

## Key Findings

- Descriptive study (unadjusted analyses)
- 30-49% of ART-naïve PLWH gained ≥5% of their baseline weight 12 months after ART initiation
- Groups with greatest weight gain after ART initiation were the most viremic and immune compromised at baseline (vice versa)
  - Suggests a significant contribution of restoration of health on weight gain in ART-naïve PLWH

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