Dolutegravir in Patients with Integrase-Resistant HIV

VIKING-4

Dolutegravir in Patients with Integrase Inhibitor Resistance
VIKING-4: Study Design

Day 1	Day 8	Week 48

Functional Monotherapy Phase	Continuation Phase
Dolutegravir: 50 mg BID or Placebo	**Dolutegravir: 50 mg BID + OBR**

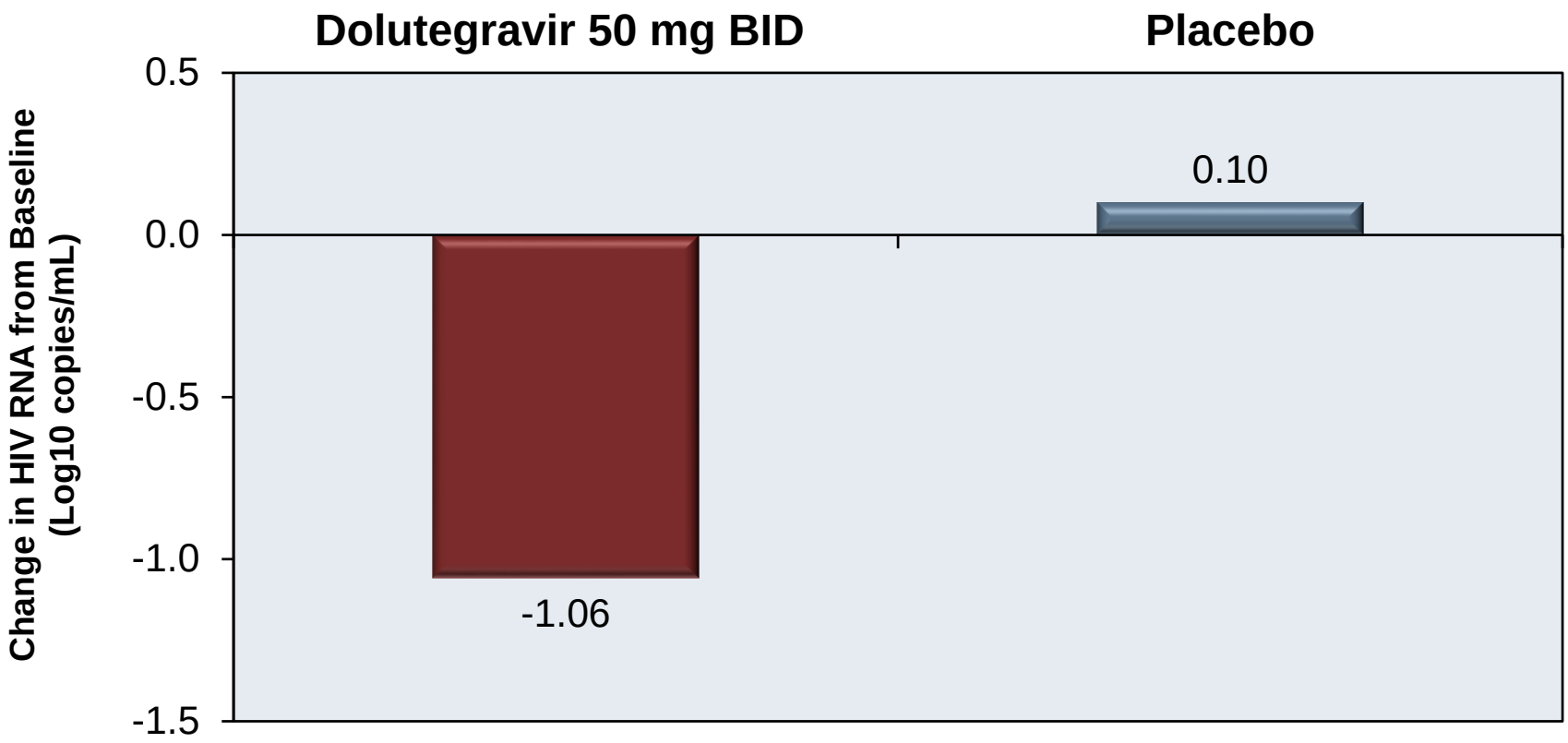
Study Design: VIKING-4

- **Background:** Single-arm, open-label, phase 3 trial to evaluate short-term antiviral efficacy of dolutegravir in persons with HIV who have integrase resistance
- **Inclusion Criteria**
  - Age ≥18 years old
  - ARV experienced, dolutegravir naïve,
  - Documented Resistance to ≥3 ARV classes, including raltegravir or elvitegravir
  - HIV RNA ≥1,000 copies/mL
- **Treatment Arms (n = 30 randomized)**
  - Day 0 to 7: Dolutegravir: 50 mg BID or Placebo
  - Day 8 to Week 24: Dolutegravir 50 mg BID + optimized background regimen

Source: Akil B, et al. Antivir Ther. 2015;20:343-8.

Dolutegravir in Patients with Integrase Inhibitor Resistance
VIKING-4: Results

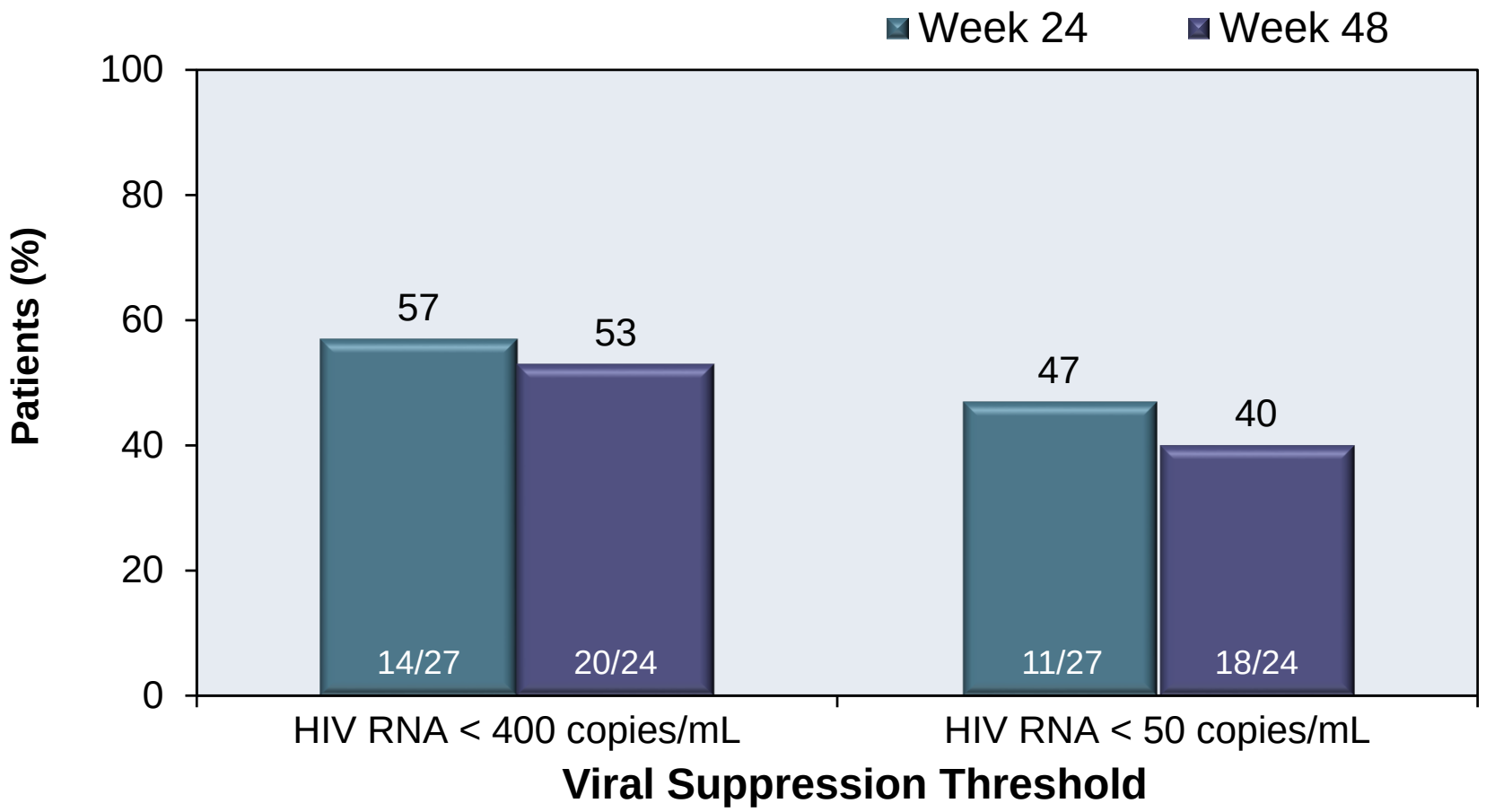
Baseline to Day 8: Change in Viral Load (in Functional Monotherapy Phase)



Source: Akil B, et al. Antivir Ther. 2015;20:343-8.

Dolutegravir in Patients with Integrase Inhibitor Resistance
VIKING-4: Results

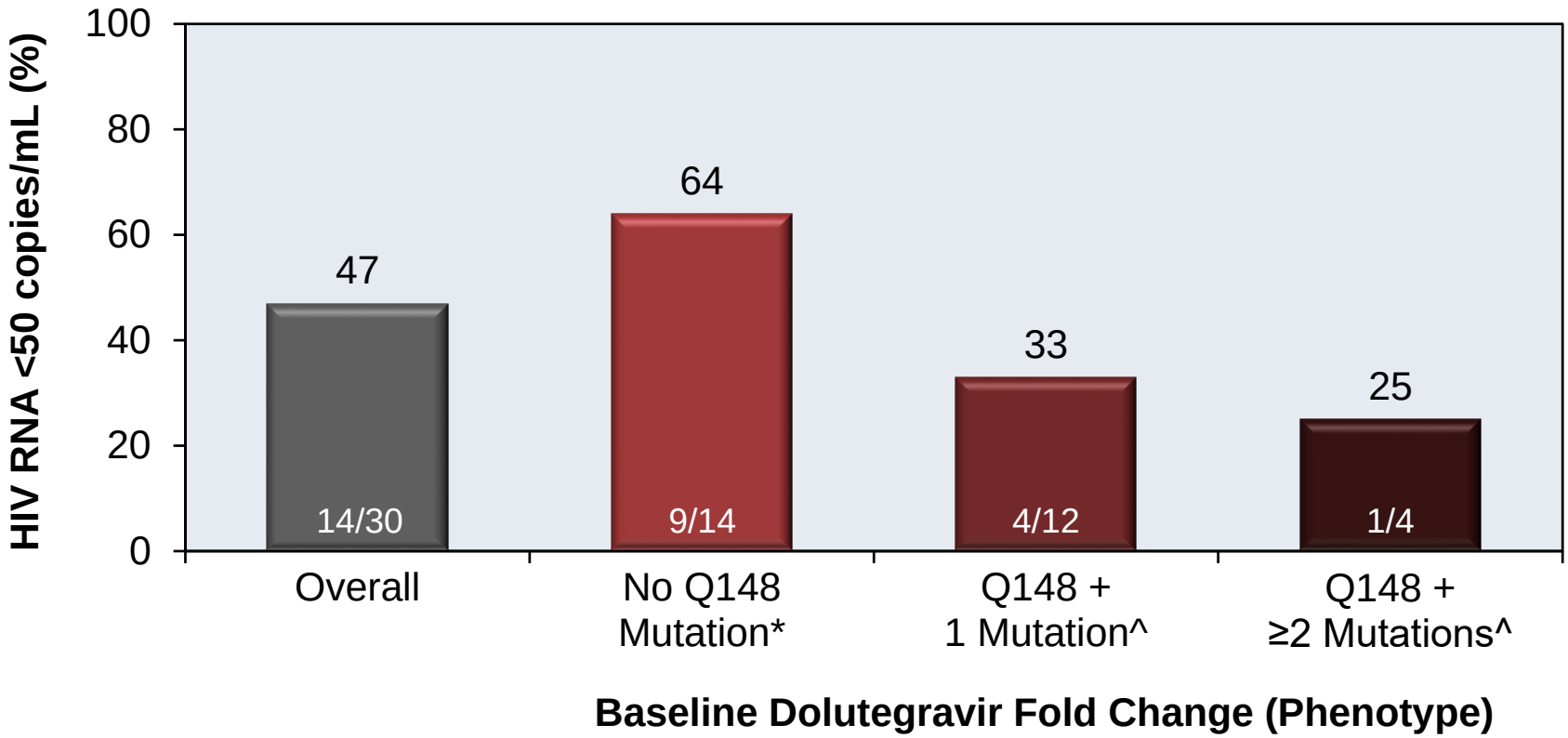
Week 24 and 48 Virologic Response in Dolutegravir-Treated Patients



Source: Akil B, et al. Antivir Ther. 2015;20:343-8.

Dolutegravir in Patients with Integrase Inhibitor Resistance
VIKING-4: Results

Week 24 Virologic Response, by Baseline Genotype

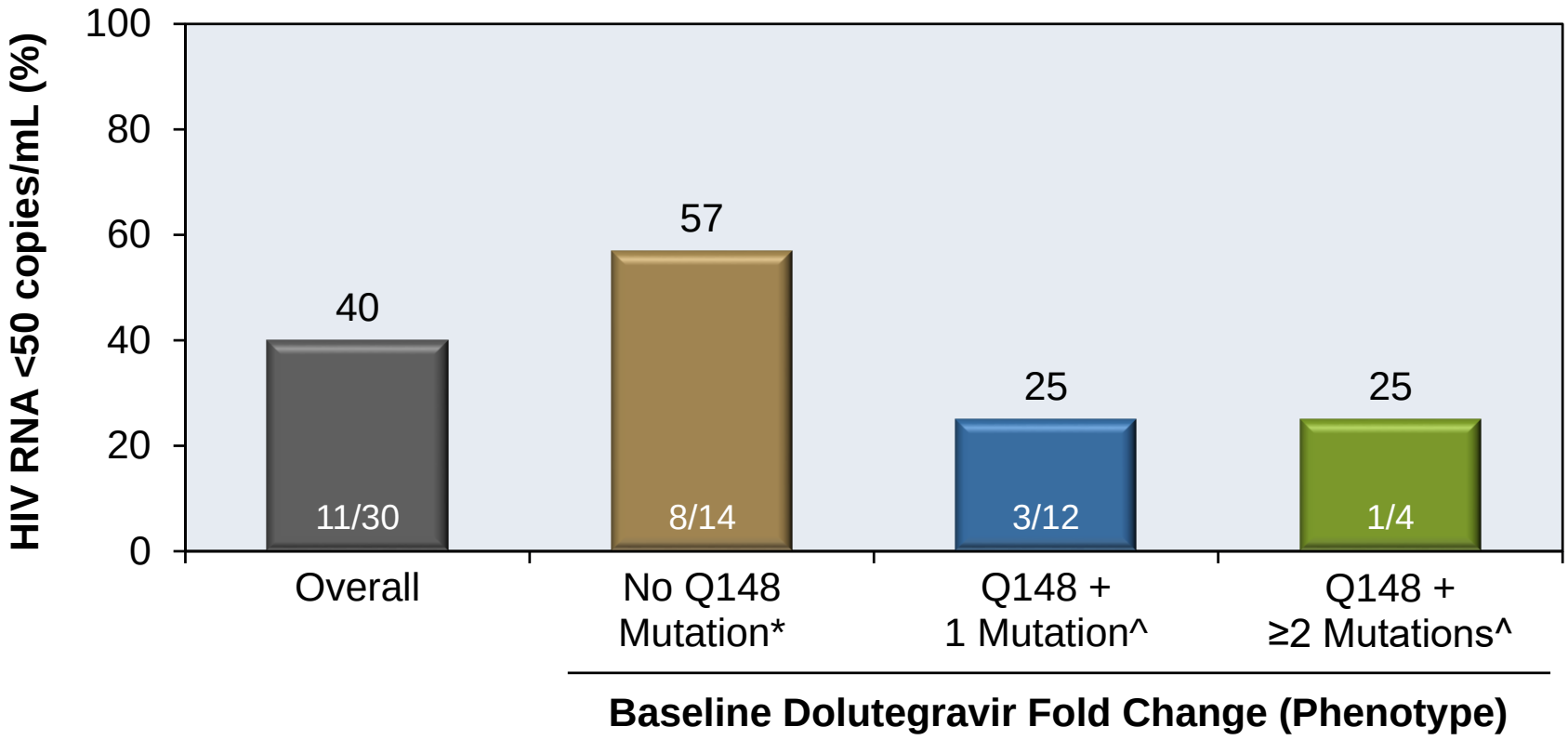


*Included primary INI-resistance mutations N155H, Y143C/H/R, T66A or E92Q or historical evidence of resistance
^Secondary mutations from G140A/C/S, E138A/K/T and L74I.

Source: Akil B, et al. Antivir Ther. 2015;20:343-8.

Dolutegravir in Patients with Integrase Inhibitor Resistance
VIKING-4: Results

Week 48 Virologic Response, by Baseline Genotype



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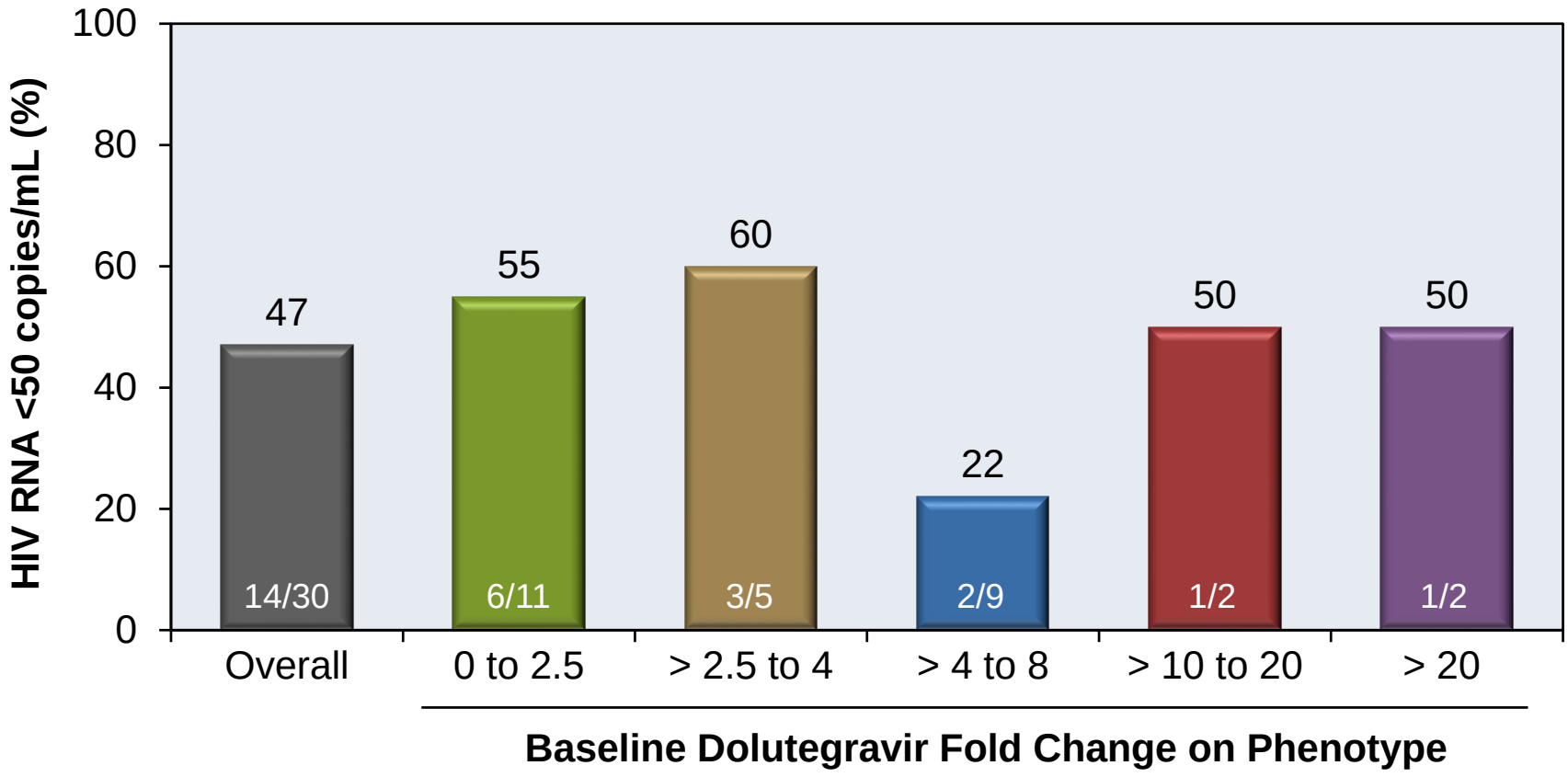
Source: Akil B, et al. Antivir Ther. 2015;20:343-8.

Dolutegravir in Patients with Integrase Inhibitor Resistance
VIKING-4: Results

Week 24 Virologic Response, by Baseline Phenotype*

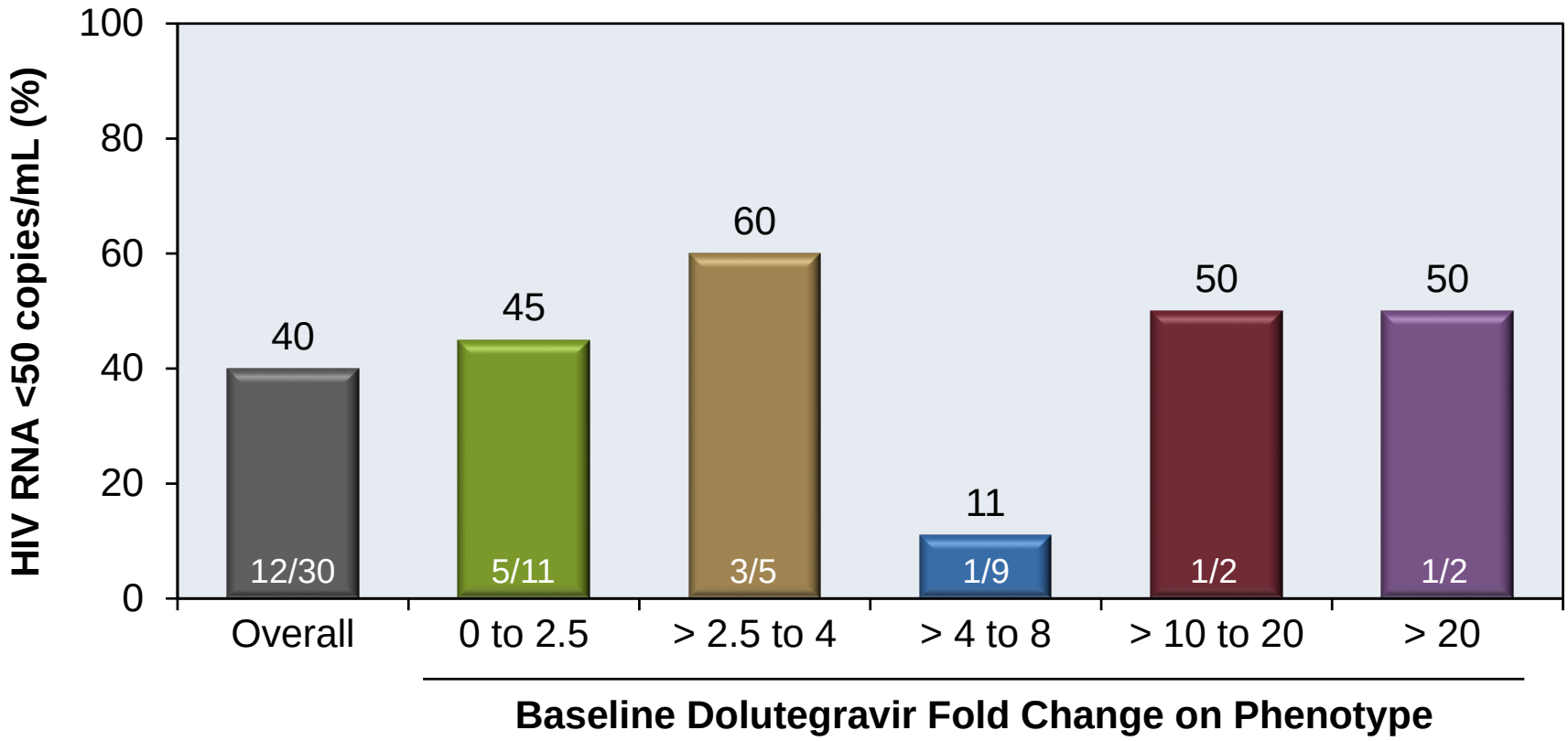


*Missing phenotypic resistance data on 1 subject

Source: Akil B, et al. Antivir Ther. 2015;20:343-8.

Dolutegravir in Patients with Integrase Inhibitor Resistance
VIKING-4: Results

Week 48 Virologic Response, by Baseline Phenotype



*Missing phenotypic resistance data on 1 subject

Source: Akil B, et al. Antivir Ther. 2015;20:343-8.

National HIV Curriculum

Dolutegravir in Patients with Raltegravir Resistance
VIKING-4: Conclusions

Conclusions: “The observed day 8 antiviral activity in this highly treatment-experienced population with INI-resistant HIV-1 was attributable to dolutegravir. Longer-term efficacy (after considering baseline ART resistance) and safety during the open-label phase were in-line with the results of the larger VIKING-3 study.”

Source: Akil B, et al. Antivir Ther. 2015;20:343-8.

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