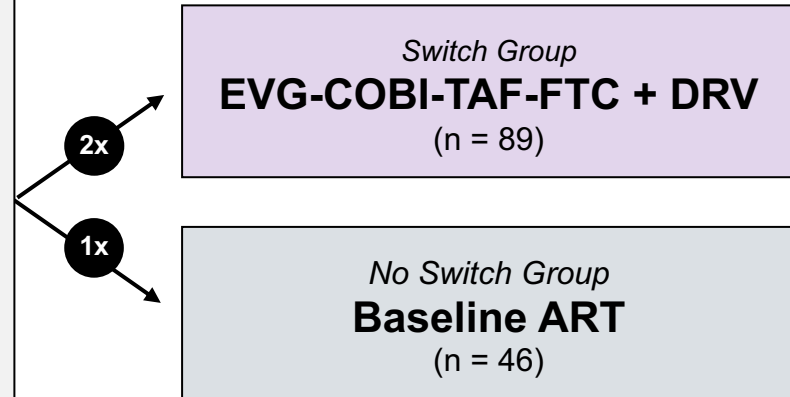


Simplification to EVG-COBI-TAF-FTC plus Darunavir
Study 119

Simplification to EVG-COBI-TAF-FTC plus DRV

Study 119: Design

- **Background:** Open-label, randomized, phase 3 trial comparing simplification to EVG-COBI-TAF-FTC plus darunavir versus continuation of baseline salvage ART regimen containing darunavir
- **Inclusion Criteria** (n = 135)
 - HIV RNA <50 copies/mL on DRV-containing regimen
 - On regimen for ≥4 months
 - At least 2 prior regimen failures and ≥2-class DRMs
 - No DRV RAMs, no INSTI resistance, ≤3 TAMs, no Q151M or T69 insertion
- **Treatment Arms**
 - EVG-COBI-TAF-FTC + DRV (Switch group)
 - Remain on baseline ART (No switch group)



***Abbreviations:** RAM = resistance associated mutation, INSTI = integrase strand transfer inhibitor, TAM's = thymidine analogue mutations

Simplification to EVG-COBI-TAF-FTC plus DRV

Study 119: Design

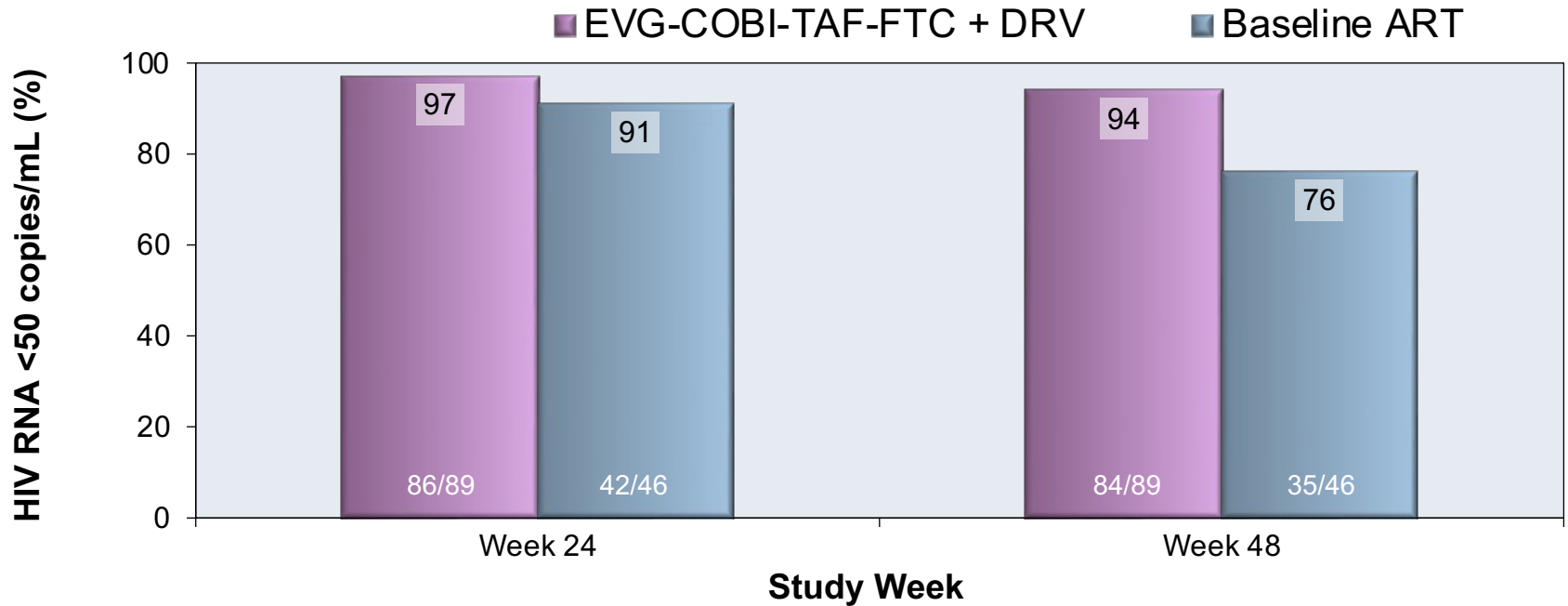
Characteristics	EVG-COBI-TAF-FTC + DRV (n = 89)	Baseline Regimen (n = 46)
Median age, years	49	47
Male	82	61
Black (or African descent)	39	57
Median CD4 count, cells/mL	519	518
Median eGFR, mL/min (Cockcroft-Gault)	99	100
Median # pills per day in ART regimen	5	5
≥6 pills per day in ART regimen, %	40	37
At least BID dosing, %	65	65
Tenofovir, %	61	54
Raltegravir, %	56	50
2 class / 3 class resistance, %	70 / 26	74 / 20
M184V/I / K65R, %	85 / 20	78 / 30
NNRTI resistance / PI resistance	89 / 38	87 / 28

Source: Huhn GD, et al. J Acquir Immune Defic Syndr. 2017;74:193-200.

Simplification to EVG-COBI-TAF-FTC plus DRV

Study 119: Results

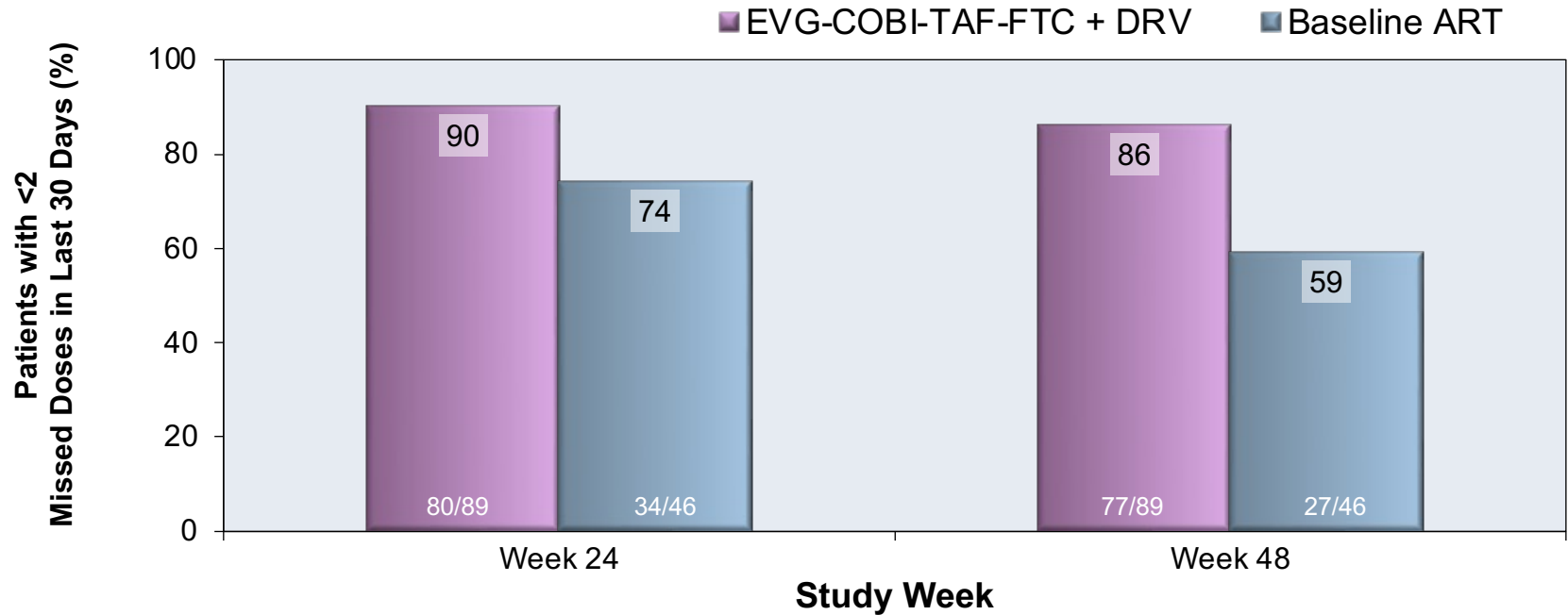
Week 24 and 48: Virologic Response (Full analysis set)



Simplification to EVG-COBI-TAF-FTC plus DRV

Study 119: Results

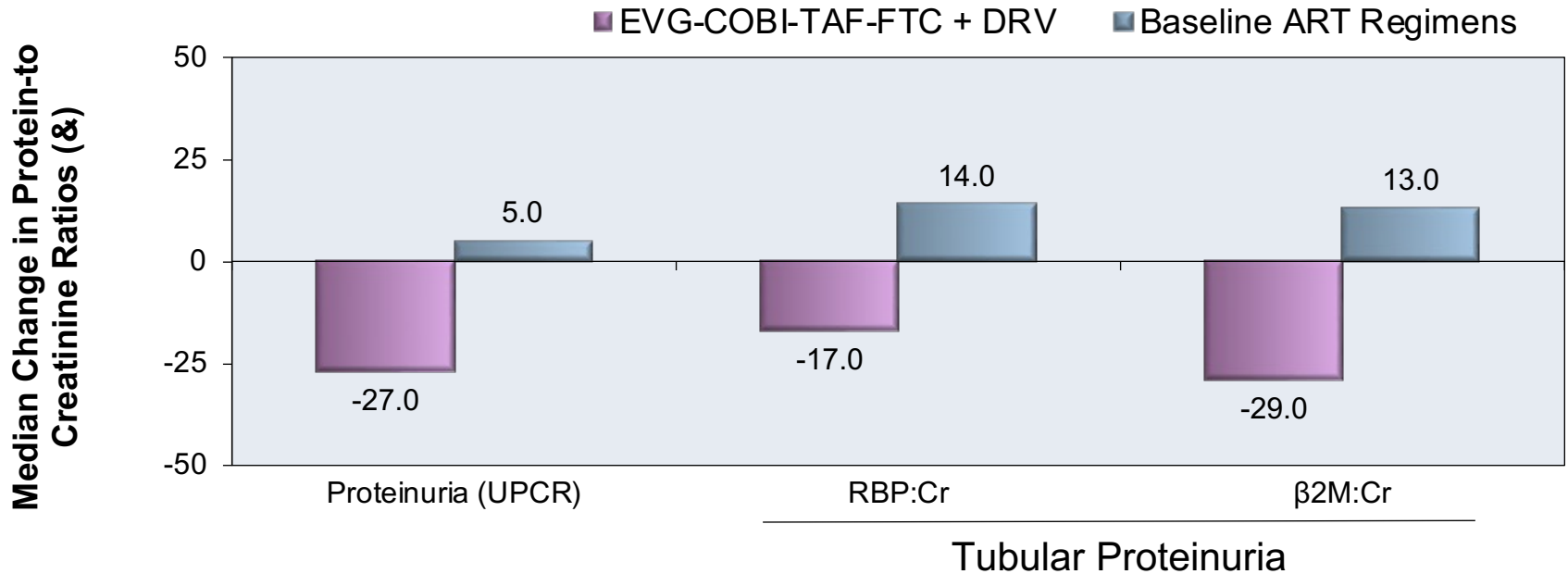
Week 24 and 48: Medication Adherence



Simplification to EVG-COBI-TAF-FTC plus DRV

Study 119: Result

Week 48: Urine Protein-to-Creatinine Ratios from Baseline



Abbreviations: RBP:Cr = retinol binding protein:creatinine ratio; beta2M:Cr = beta-2 microalbumin:creatinine ratio

Simplification to EVG-COBI-TAF-FTC plus DRV

Study 119: Conclusions

Conclusions: “This study demonstrated that regimen simplification from a 5-tablet regimen to the 2-tablet, once-daily combination of E/C/F/TAF plus DRV has durable maintenance of virologic suppression and improvements in specific markers of renal safety. Such a strategy may lead to greater adherence and improved quality of life.”

Acknowledgments

The **National HIV Curriculum** is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$1,021,448 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.

