

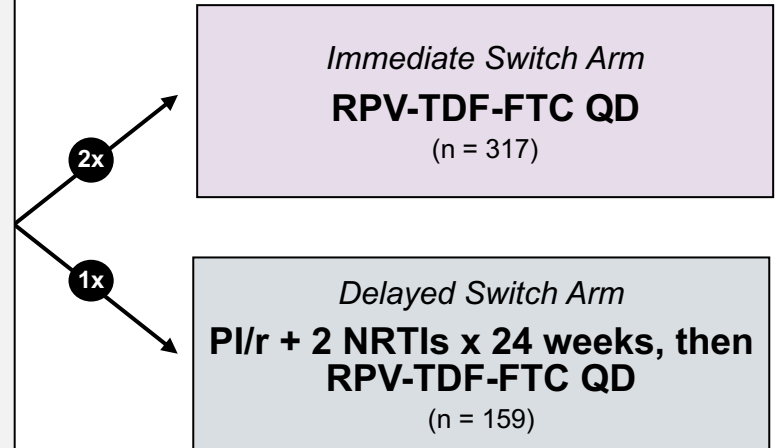
Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen

SPIRIT STUDY

Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen

SPIRIT: Study Design

- **Background:** Open-label, randomized, phase 3b trial evaluating switching from ritonavir-boosted PI plus 2 NRTIs to single-tablet regimen of rilpivirine-tenofovir DF-emtricitabine once daily
- **Inclusion Criteria**
 - Age ≥ 18 years
 - HIV RNA < 50 copies/mL for ≥ 6 months
 - On PI with ritonavir ≥ 6 months
 - No known resistance to study drugs
- **Treatment Arms**
 - Rilpivirine-tenofovir DF-emtricitabine
 - PI with ritonavir (PI/r) + 2 NRTIs x 24 weeks, then rilpivirine-tenofovir DF-emtricitabine



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SPIRIT: Study Design

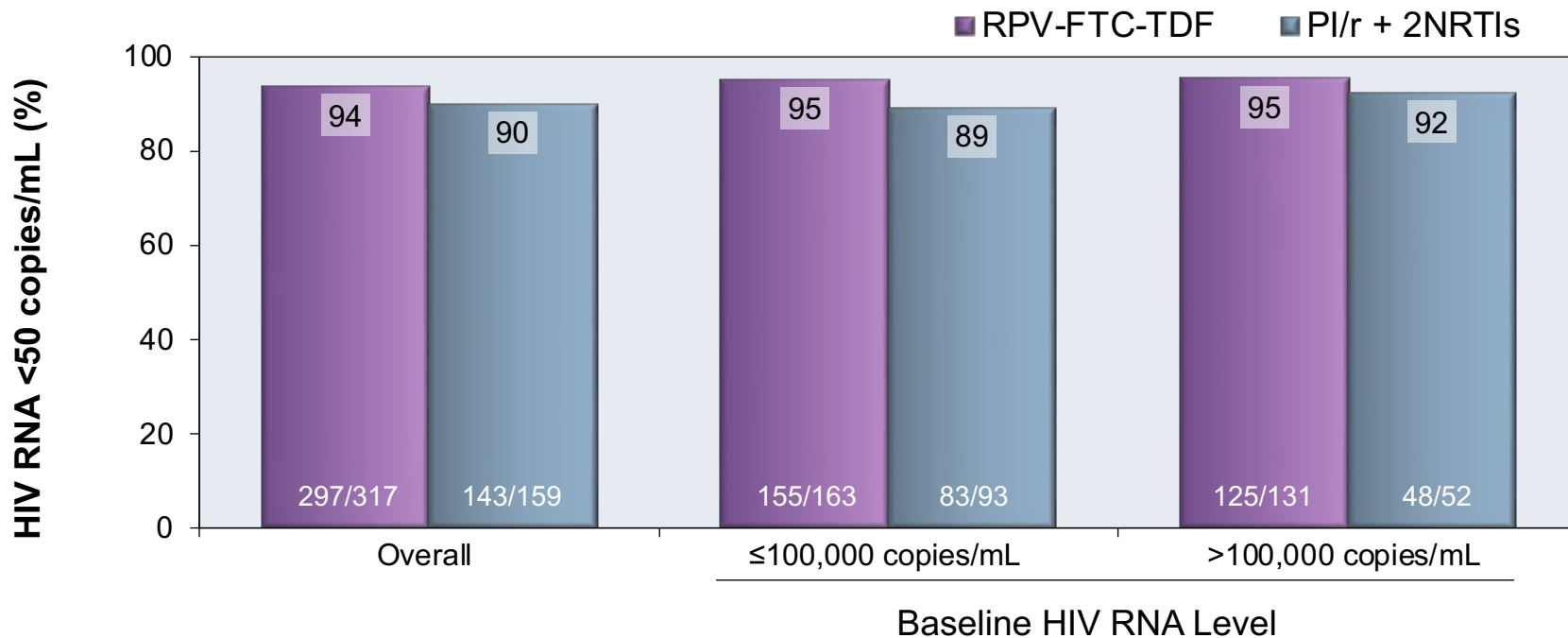
Baseline Antiretroviral Regimens		
	Immediate Switch Arm (n = 317)	Delayed Switch Arm (n= 159)
NRTI at Screening		
TDF-FTC	80.4%	81.8%
ABC-3TC	13.2%	13.2%
Ritonavir-Boosted PI at Screening		
Atazanavir	38.5%	34.0%
Lopinavir	30.6%	36.5%
Darunavir	19.9%	20.8%
Fosamprenavir	7.9%	7.5%
Saquinavir	1.9%	1.3%

Source: Palella FJ, et al. AIDS. 2014;28:335-44.

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SPIRIT: Results

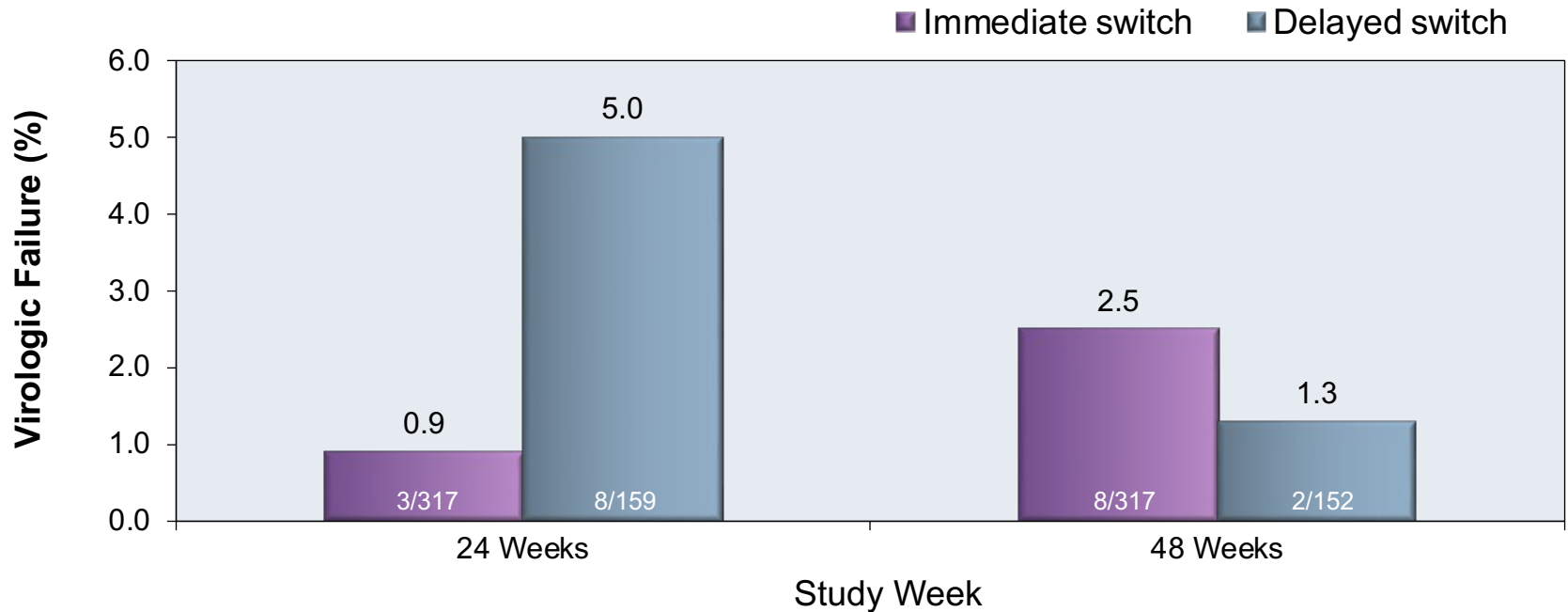
Week 24 Virologic Response (Intent-to-Treat Analysis)



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SPIRIT: Results

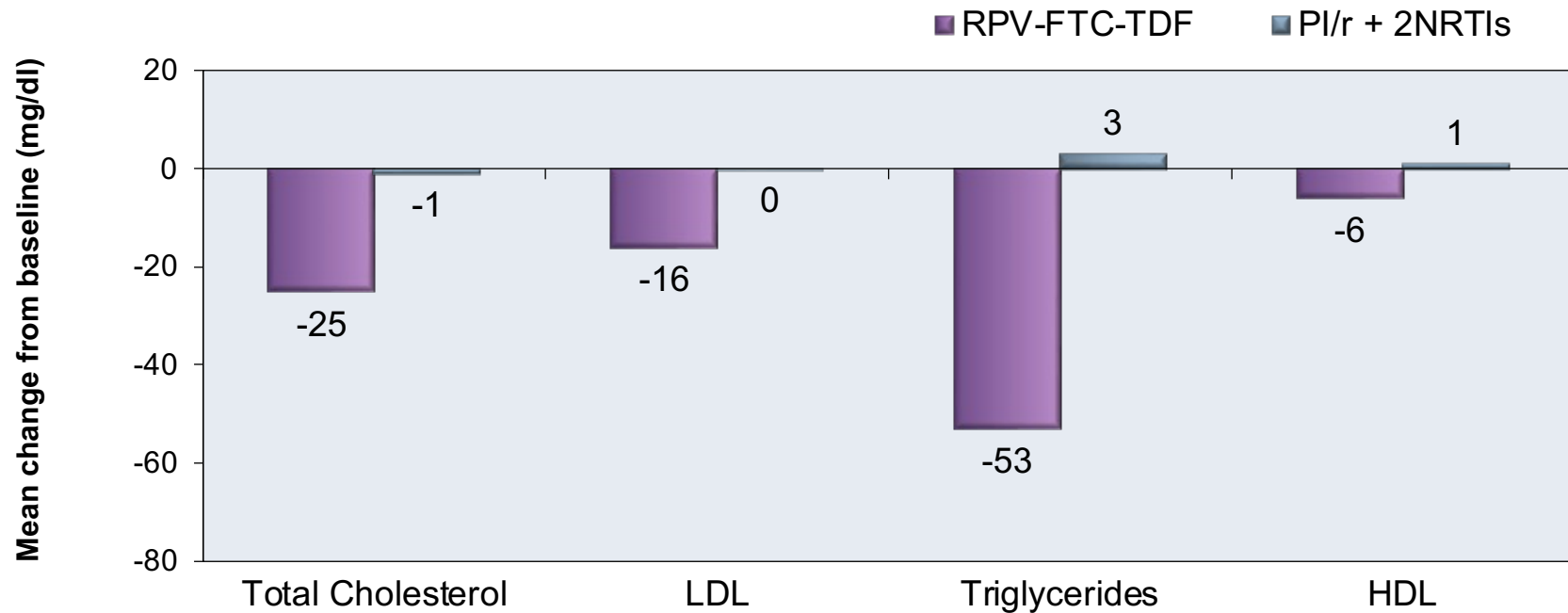
Virologic Failure (HIV RNA ≥ 50 copies/mL) at Weeks 24 and 48



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SPIRIT: Results

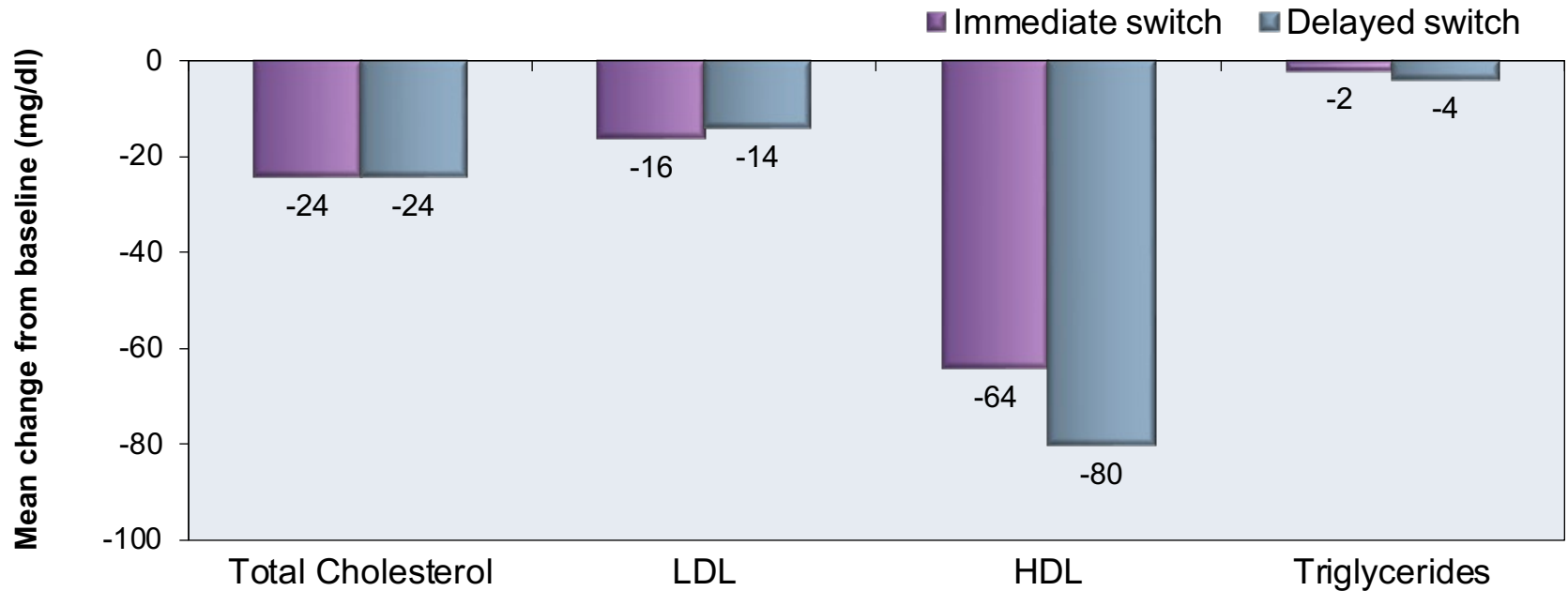
Week 24: Change in Plasma Lipids from Baseline



Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen

SPIRIT: Result

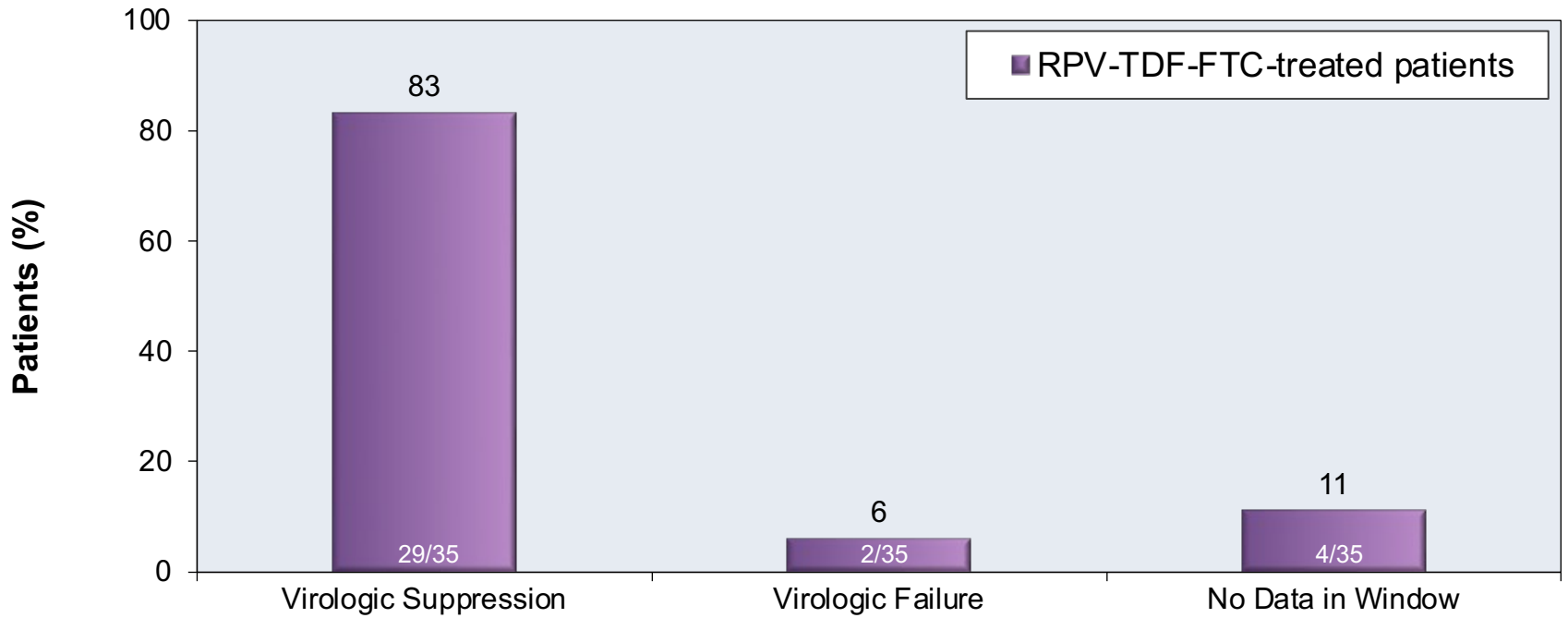
Week 48: Change in Plasma Lipids from Baseline



Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen

SPIRIT: Result

Week 48 Virologic Outcomes in Patients with Resistance Mutations*



*Pre-existing NRTI or NNRTI resistance mutations by baseline proviral DNA or historical RNA genotype

Switch to RPV-TDF-FTC from Ritonavir-boosted PI Regimen Spirit: Conclusions

Conclusion: “Switching to the STR RPV/FTC/TDF from an RTV-boosted protease inhibitor regimen in virologically suppressed, HIV-1-infected participants maintained virologic suppression with a low risk of virologic failure, while improving total cholesterol, LDL, and triglycerides.”

Acknowledgments

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