

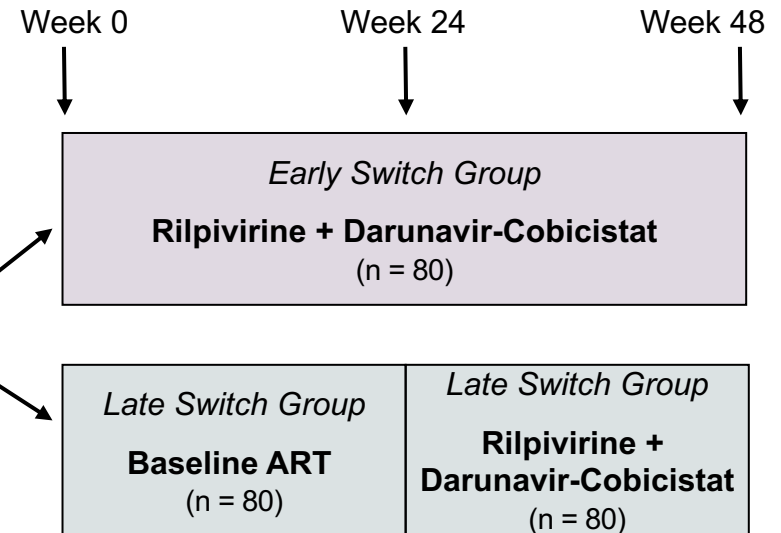
Rilpivirine + Darunavir-Cobicistat Dual ART as an Alternative to Standard 3-Drug ART

PROBE 2

Rilpivirine + Darunavir-Cobicistat versus Standard 3-Drug ART

PROBE 2 Trial: Background

- **Background:** Randomized, open label, parallel group, active controlled trial comparing a switch to dual ART maintenance therapy with rilpivirine + darunavir-cobicistat versus continued 3-drug ART for individuals with a suppressed viral load
- **Enrollment Criteria**
 - Age ≥ 18 years
 - HIV RNA < 50 copies/mL for ≥ 6 months
 - Taking an NNRTI, INSTI, or boosted PI, along with a 2-NRTI backbone
 - No INSTI or PI resistance-associated mutations
 - No chronic hepatitis B
 - Not pregnant or breastfeeding



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PROBE 2 Trial: Baseline Characteristics

Baseline Characteristic (%)	Early Switch (n = 80)	Late Switch (n = 80)
Main NRTI backbone agent		
ABC	22.5	12.5
TAF	30.0	35.0
TDF	47.5	52.5
Core (anchor) agent		
PI	21.3	17.5
NNRTI	72.4	65.0
INSTI	6.3	17.5
Number of pills in regimen		
1	55.0	67.5
2	36.3	28.8
3	8.8	3.8

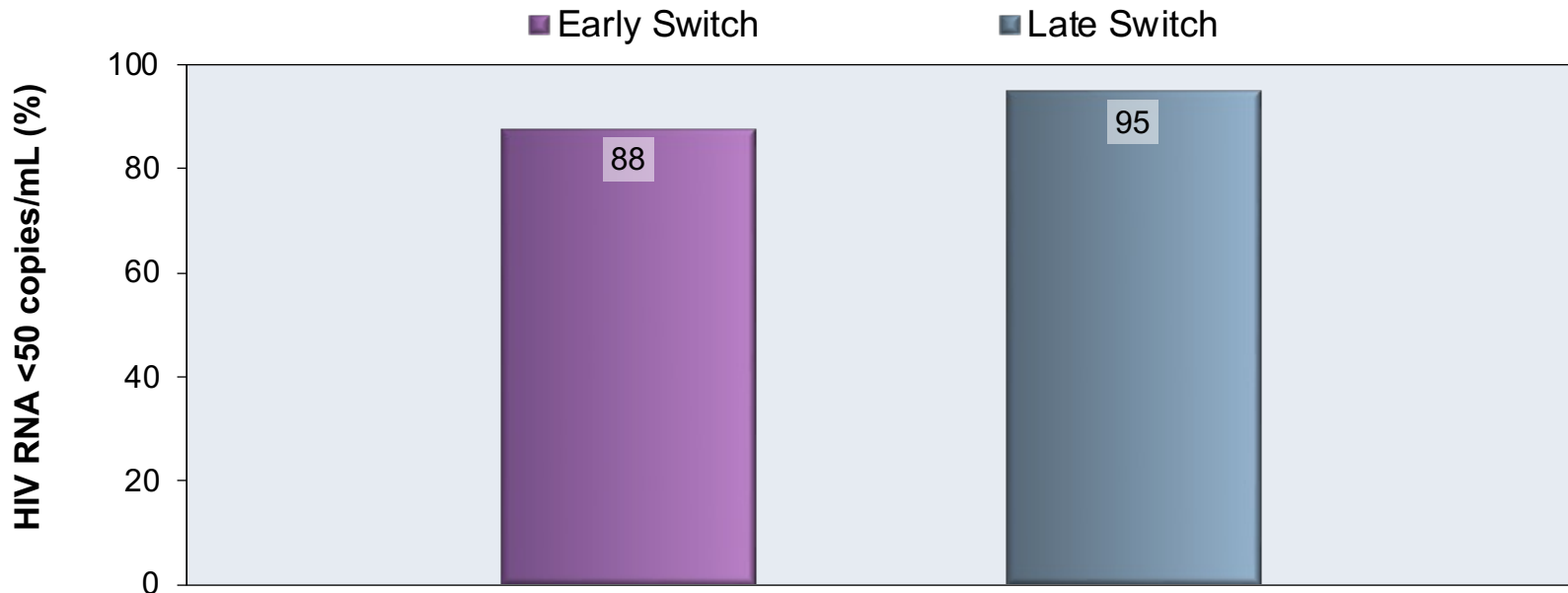
Overall, 82.5% participants were men, 95.6% were white, and median age was 50 years

Source: Maggiolo F, et al. *Antivir Ther.* 2021;26:51-7.

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PROBE 2 Trial: Baseline Characteristics

Week 48 Virologic Response (Intention-to-Treat Analysis)



Virologic failure (HIV RNA >50 copies/mL) occurred in zero participants in early switch group and 2 participants in late switch group, though with no emergent drug resistance mutations.

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PROBE 2 Trial: Week 48 Results

Variable (medians)	Early Switch (n = 80)			Late Switch (n = 80)		
	Baseline	Week 48	P Value	Baseline	Week 48	P Value
Total cholesterol, mg/dL	200	208	0.51	188	210	<0.001
HDL, mg/dL	48	48	0.32	46	46	0.783
LDL, mg/dL	125	135	0.002	125	139	<0.001
Triglycerides, mg/dL	126	156	0.004	125	164	0.001
Bone stiffness, g/cm ² *	83.9	86.0	0.017	85.4	87.1	0.894
Body weight, kg	69.5	69.0	NR	73.0	73.0	NR

*Bone stiffness measured by quantitative ultrasound

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PROBE 2 Trial: Conclusions

Conclusions: “The combination of rilpivirine plus darunavir/cobicistat sustained virological suppression, was associated with a low frequency of virological failure, and had a favorable safety profile, which support its use as a nucleoside reverse transcriptase inhibitor-sparing and integrase inhibitor-sparing alternative to three-drug regimens.”

Acknowledgments

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