

Effects of Switching ZDV to TDF on Fat Distribution and Lipoatrophy

RECOMB

Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Fat Distribution): Study Design

Study Design: RECOMB

- **Background:** Prospective, randomized, open-label, multicenter trial conducted in Spain comparing effect of continuation of ZDV-3TC versus switching to TDF-FTC on limb fat mass and other laboratory parameters
- **Inclusion Criteria:**
 - Adults with HIV infection
 - Receiving a cART regimen including ZDV and 3TC* plus an NNRTI or PI for ≥ 6 months
 - HIV RNA < 50 copies/mL at last two consecutive checks
- **Regimens**
 - Switch ZDV-3TC to TDF-FTC
 - Continue ZDV-3TC

Switch Arm
Tenofovir DF-Emtricitabine
(n = 39)

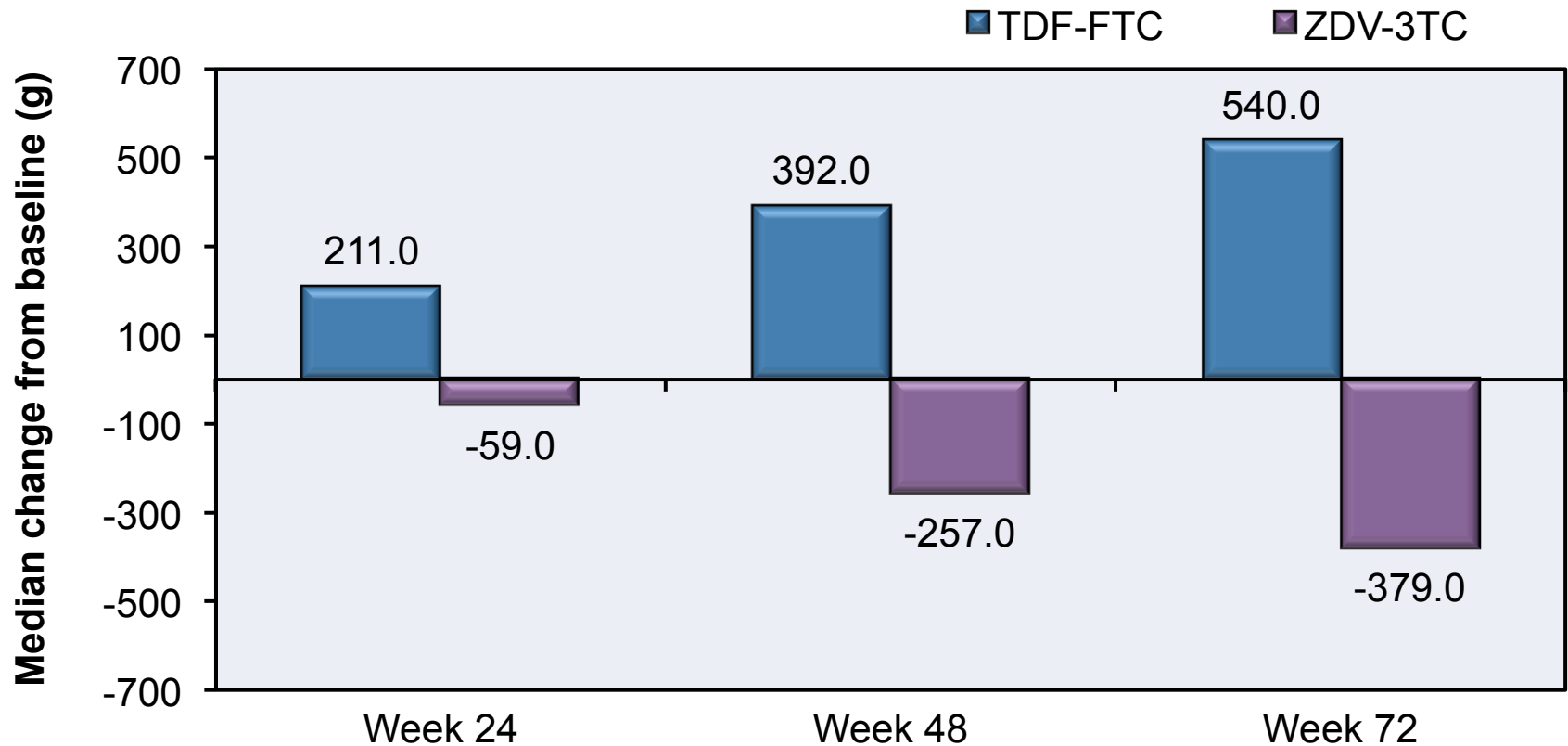
Continuation Arm
Zidovudine + Lamivudine*
(n = 41)

*Either as fixed-dose zidovudine-lamivudine or as separate zidovudine and lamivudine tablets

Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Fat Distribution): Results

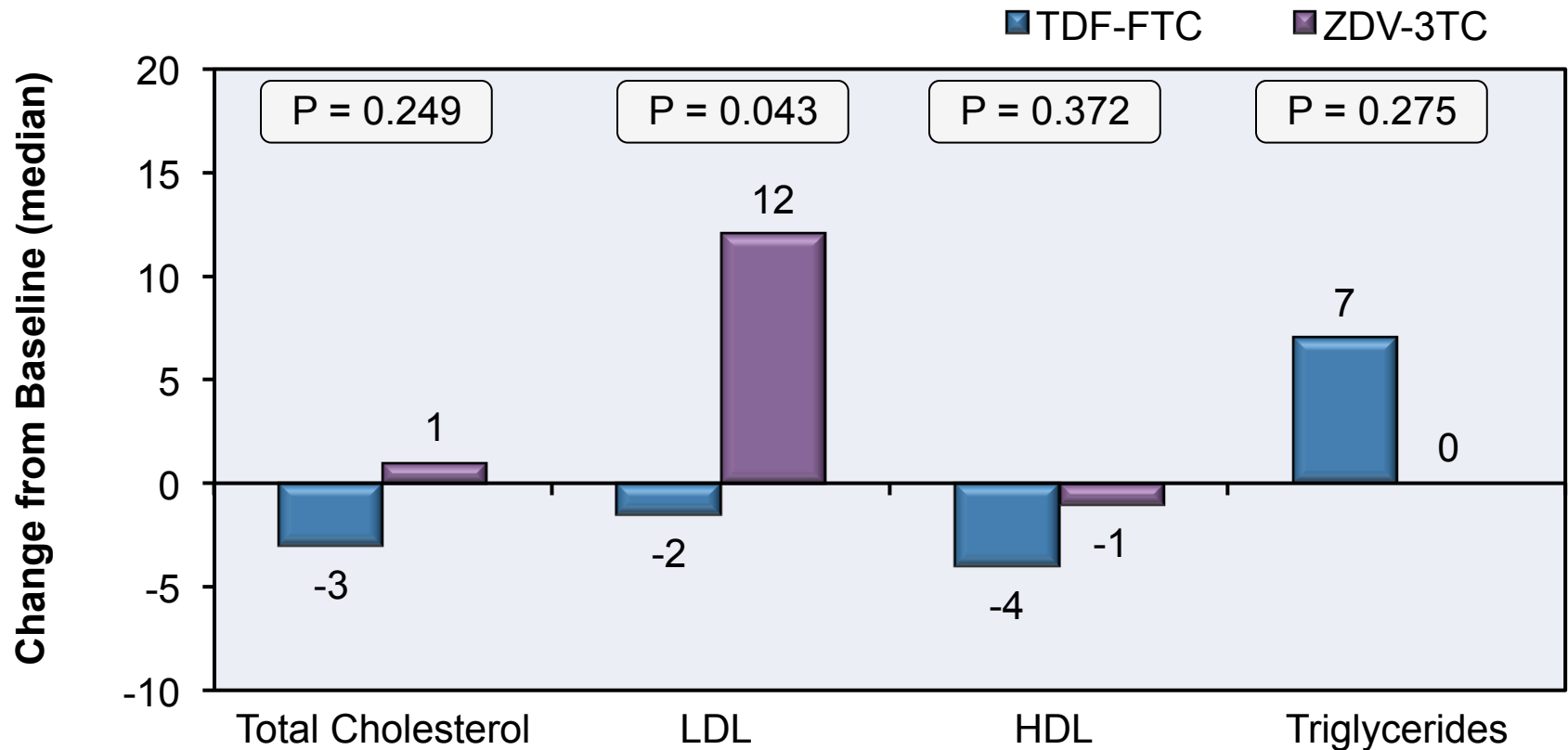
Change in Limb Fat Mass from Baseline (Measured by DXA)



Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Fat Distribution): Results

Week 72: Change in Plasma Lipids



Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Fat Distribution): Results

Week 72: Change in Laboratory Parameters from Baseline

Laboratory Results: Change from Baseline to Week 72 (Median Values)			
	TDF-FTC	ZDV-3TC	P Value
Trunk fat content (kg)	0.354	0.526	0.897
Total body fat (kg)	0.786	0.334	0.307
Haemoglobin (g/dL)	1.0	-0.1	0.0002
Hematocrit (%)	2.3	0.0	0.0014
Creatinine (mg/dL)	0.05	-0.02	0.001
Lactic acid (mmol/L)	-0.17	0.07	0.024

Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy RECOMB (Fat Distribution): Conclusions

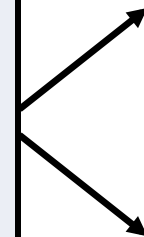
Conclusions: “Switching from a ZDV/3TC-based to a TDF/FTC-based regimen led to a statistically significant improvement in limb fat, in contrast to the progressive loss of limb fat in subjects continuing ZDV/3TC.”

Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Lipoatrophy): Study Design

Study Design: RECOMB

- **Background:** Prospective, randomized, open-label, multicenter trial conducted in Spain comparing effect of continuation of ZDV-3TC versus switching to TDF-FTC on fat mass ratio (FMR), an indicator of fat distribution (lipoatrophy defined as $FMR \geq 1.5$)
- **Inclusion Criteria:**
 - HIV-infected men enrolled in the RECOMB study (women excluded because FMR cutoff values for women not defined)
 - Receiving a cART regimen including ZDV and 3TC* plus an NNRTI or PI for ≥ 6 months
 - HIV RNA < 50 copies/mL at last two consecutive checks
- **Regimens**
 - Switch ZDV-3TC to TDF-FTC
 - Continue ZDV-3TC



Switch Arm
Tenofovir DF-Emtricitabine
(n = 28)

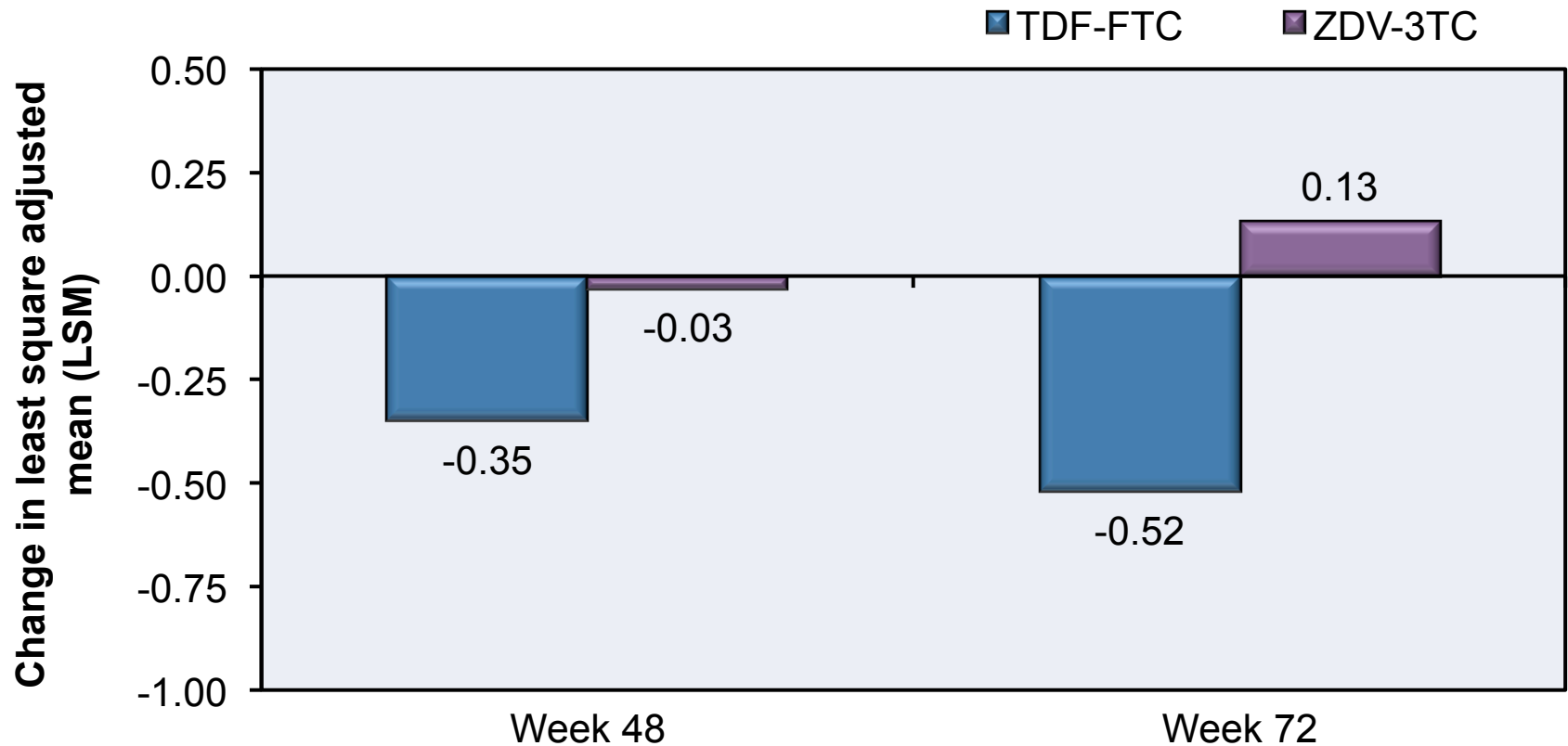
Continuation Arm
Zidovudine + Lamivudine*
(n = 37)

*Either as fixed-dose zidovudine-lamivudine or as separate zidovudine and lamivudine tablets

Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Lipoatrophy): Results

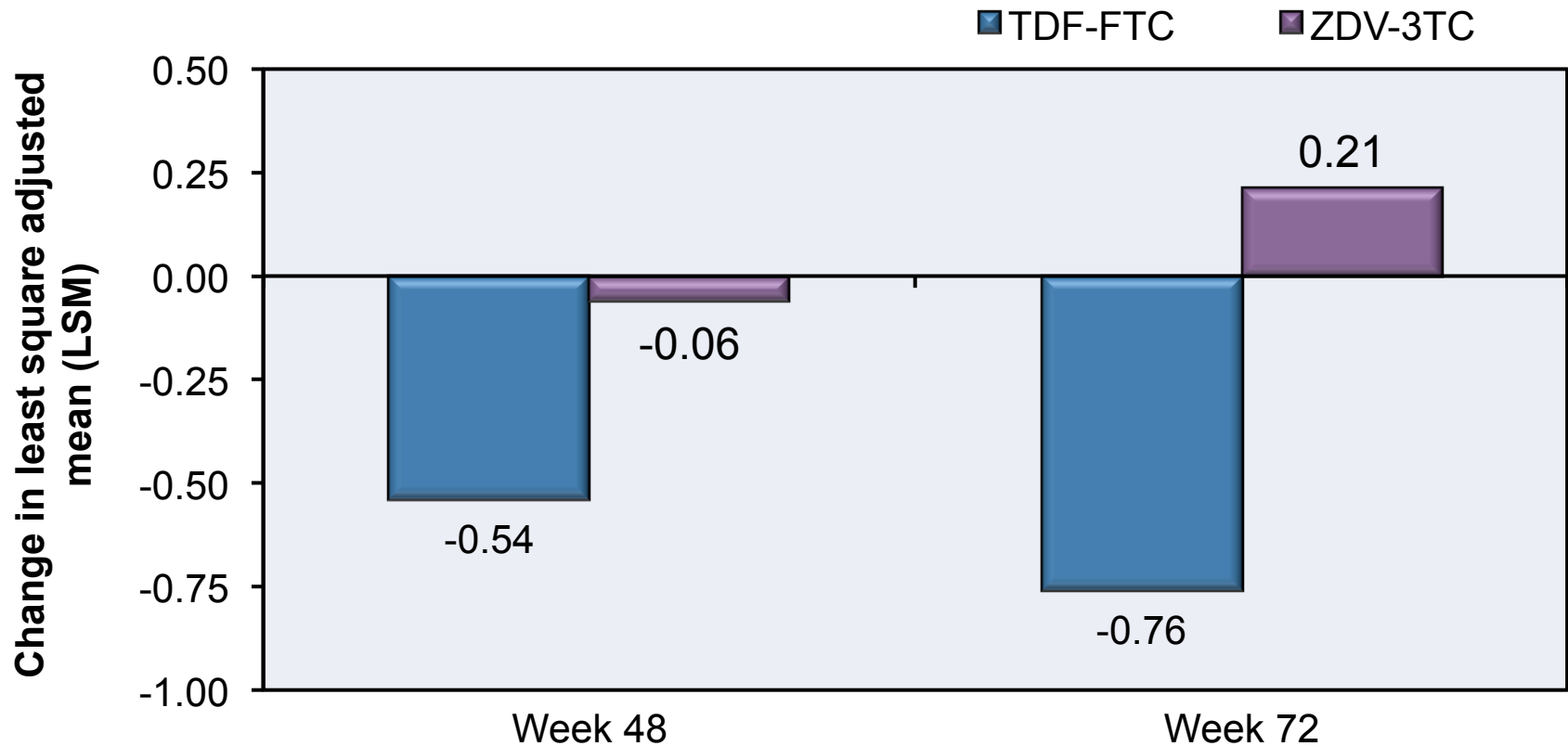
Change in Fat Mass Ratio (FMR) from Baseline (All Subjects)



Effects of Switching ZDV to TDF on Fat Distribution & Lipoatrophy

RECOMB (Lipoatrophy): Results

Change in FMR from Baseline (Subjects with FMR ≥ 1.5 at Study Entry)



Effects of Switching AZT to TDF on Fat Distribution & Lipoatrophy RECOMB (Lipoatrophy): Conclusions

Conclusions: “Switching from ZDV/3TC to FTC/TDF led to an improvement in FMR, compared with progressive worsening of FMR in subjects receiving ZDV/3TC, showing that fat mass not only increased but was also distributed in a healthier way after the switch.”

Acknowledgment

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The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.

