

Poster presentation

48-week outcomes following switch from AZT/3TC to FTC/TDF (TVD) vs. continuing on AZT/3TC: 48-week interim analysis of the RECOMB trialE Ribera^{*1}, B Clotet², E Martínez³, V Estrada⁴, J Sanz⁵, J Berenguer⁶, R Rubio⁷, F Pulido⁷, M Larrouse³, A Curran¹, E Negrodo², P Ferrer⁸ and ML Álvarez⁸

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from Ninth International Congress on Drug Therapy in HIV Infection
Glasgow, UK. 9–13 November 2008

Published: 10 November 2008

Journal of the International AIDS Society 2008, **11**(Suppl 1):P54 doi:10.1186/1758-2652-11-S1-P54

This abstract is available from: <http://www.jiasociety.org/content/11/S1/P54>

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Purpose of the study

To compare changes in total limb fat by DEXA scan assessment after switching from an AZT/3TC backbone to TVD vs. maintaining an AZT/3TC regimen.

Methods

72 weeks, open label, randomised, controlled study. Virologically-suppressed HIV-infected patients (<50 c/mL) on HAART containing AZT/3TC (plus either an NNRTI or a PI) were assigned to either switch their AZT/3TC backbone to TVD or continue current AZT/3TC-containing regimen. Stratification was performed by third agent of HAART (either NNRTI or PI).

Summary of results

80 patients included (39 TVD; 41 AZT/3TC). Mean age was 44 years. Patients were predominantly male (81%). The median CD4 cell count at baseline was higher in the TVD vs AZT/3TC arm (655 vs. 504 cel/mm³; $p = 0.037$). (Tables 1 and 2.)

Five patients discontinued due to an adverse event before week 24; one in the TVD group (upper abdominal pain) and four in AZT/3TC group (two renal cholic, one anaemia, one lactic acidosis). Changes from BL in GFR (CG) were -11.8 for TVD and -3.6 mL/min for AZT/3TC.

Conclusion

Through 48 weeks, switching from a suppressive HAART regimen containing AZT/3TC to TVD, was well tolerated, maintained efficacy and led to a significant improvement in limb fat content. Additionally, haemoglobin and hematocrit significantly improved for patients switched from AZT/3TC to TVD.

Table 1: Efficacy outcomes at Week 48.

	TVD	AZT/3TC	p-value
% of Pts with HIV RNA < 50 c/mL (M = F)	92%	78%	0.12
Median CD4 count change (cell/mm ³)	+60.5	+9	0.079

M = F denotes missing = failure analysis.

Table 2: Week 48 median changes from BL in limb fat, haematology and lipids

	TVD arm (BL)	TVD arm (Week 48 – BL)	AZT/3TC arm (BL)	AZT/3TC arm (Week 48 – BL)	p-value
Total limb fat (g)	3565	+392	3946	-257	0.001
Hb (g/dL)	14.6	+0.9	14.9	+0.3	0.007
Hematocrit (%)	42.6	+2.7	42.0	+1.0	0.001
Total Cholesterol (mg/dL)	187.0	+4.5	189.0	+1.0	0.97
LDL-c (mg/dL)	109.0	+7.0	107.5	+5.0	0.66
HDL-c (mg/dL)	49.0	-2.0	49.5	+2.0	0.29
TG (mg/dL)	110.0	+1.5	120.0	+4.0	0.96

BL = baseline.

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