

Impact of Dual Therapy on Weight Gain and Metabolic Outcomes in Naïve People living with HIV (PLHIV) with CD4 Counts <200 Cells/mm³: Findings from the DOLCE Study

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M. Figueroa¹, C. Brites², D. Cecchini³, A. Santos Ramalho Teixeira⁴, J.L. Francos⁵, M. Lacerda⁶, J. Valdez Madruga⁷, E. Sprintz⁸, D. Converso¹, P. Parenti⁹, T. Newman¹⁰, Lobato Souza, C. Perez¹, G. Mernies¹, M. Rolon¹¹, O. Sued¹, P. Cahn¹

¹Fundación Huesped, Research Department, Buenos Aires, Argentina; ²Fundação Bahiana de Infectologia, Canela, Salvador de Bahia, Brazil; ³Hospital General de Agudos Dr. Cosme Argerich, Buenos Aires, Argentina; ⁴Nova Iguaçu Prefeitura, Nova Iguaçu, Rio de Janeiro, Brazil; ⁵Hospital de Infectiosas Francisco Javier Muñoz, Buenos Aires, Argentina; ⁶Fundação de Medicina Tropical do Amazonas, Manaus, Brazil; ⁷Centro de Referência e Treinamento DSTAIDS, São Paulo, Brazil; ⁸Hospital de Clínicas de Porto Alegre, Porto Alegre, Brazil; ⁹Instituto Caicí, Rosario, Santa Fe, Argentina; ¹⁰Instituto de Infectología Emilio Ribas, San Pablo, Brazil; ¹¹Hospital Juan A Fernandez, Buenos Aires, Argentina; ¹²Pan American Health Organization, Washington D. C., United States

BACKGROUND

Weight changes can impact health outcomes. While weight loss has been associated with advanced HIV disease, individuals with low CD4 counts may experience weight gain, potentially associated with antiretroviral therapy (ART) initiation. We report the effects of dolutegravir-based dual and triple therapy on weight, glucose, and lipid profiles after 48 weeks of treatment in PLHIV with low CD4 counts.

RESULTS

Out of 230 subjects, 153 were in the DT arm and 77 in TT. 75.7% were male, 24.3% female; 42.6% Hispanic/Latino, 38.7% White, and 15.2% Black. Median baseline weight was 64 kg for DT and 63 kg for TT, with 48-week weights of 74 kg (DT) and 71 kg (TT). Weight increase was 14% (DT) vs 11% (TT) ($p=0.017$). Median baseline BMI was 22.6 for DT and 22.7 for TT, significantly increasing by W48 in both arms: DT 25.8, TT 25.5. Metabolic changes were also observed. The median increase in total cholesterol, LDL-C, and HDL-C was less in TT: 22% vs 5% (cholesterol, $p<0.001$) and 22% vs 4% (LDL-C, $p<0.001$). Triglycerides increased more in the TT group (17% vs 0%). Despite the increase, the values remained within the upper normal limit. Blood glucose remained unchanged in both arms during the 48 weeks. (Table 1)

Severely immuno deficiency treatment-naïve PWH initiating **dual or triple ARV therapy** developed significant **weight gain of 10 Kg and 8 Kg** respectively ($p:0.01$). BMI changed from low to normal in both arms. Cholesterol (total, HDL and LDL) increase was higher with DT, while triglycerides increased more with TT.

METHODS

The DOLCE study reported comparable rates of virologic suppression between dual therapy (DT) and triple therapy (TT) in PLHIV with CD4 counts <200 cells/mL. Key outcomes included weight, BMI, glucose, and lipid profiles. Metabolic changes were analyzed with a mixed-effect linear regression model, controlling for baseline values, sex, and race.



CONCLUSIONS

Both DT and TT resulted in significant weight gain and lipid changes in HIV-positive individuals with low CD4 counts, with no effect on glucose levels. The weight gain likely reflects a return to health due to ART initiation in this severely immunosuppressed population.



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Table 1. BSL and Week 48 Metabolic Outcomes. Median percentage change from baseline

Median (IQR)	DT (n=152)			TT (n=77)		
	BSL Median*	W48 Median*	Median % change**	BSL Median*	W48 Median*	Median % change**
Weight	64 (57-62)	74 (66-82)	+14 (9;27)	63 (58-73)	71 (65-85)	+11 (4;20)
Total cholesterol	137 (119-169)	172 (149-196)	+22 (4;41)	142 (123-170)	155 (134-170)	+5 (-8;20)
HDL	37 (29-45)	48 (39-57)	+29 (10;52)	36 (29-46)	42 (36-52)	+14 (0;47)
LDL	77 (59-97)	98 (78-115)	+22 (1;52)	82 (63-97)	86 (75-102)	+4 (-14;27)
Triglycerides	116 (82-152)	105 (73-144)	0 (-25;27)	101 (83-158)	87 (63-111)	-17 (-42;10)
Glucose	85 (80-92)	87 (81-95)	+1 (-6;11)	85 (80-90)	88 (83-95)	+5 (-5;14)

* Unit weight kg; unit cholesterol, HDL, LDL, triglycerides, glucose mg/dl

** Median percentage increase between baseline and week 48. Percentage change was calculated at each specific time point for each subject as (concentration [week 48] - concentration [baseline]) / (concentration [baseline]) x 100.

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