

OAB36 Co-morbidities: Beyond the heart

OAB3606LB

Non-inferior efficacy and less weight gain when switching to DTG/3TC than when switching to BIC/FTC/TAF in virologically suppressed people with HIV (PWH): the PASO-DOBLE (GeSIDA 11720) randomized clinical trial.

P. Ryan¹, J.L. Blanco², M. Masia³, L. Garcia-Fraile⁴, M.J. Crusells⁵, P. Domingo⁶, A. Curran⁷, R. Guerri-Fernandez⁸, E. Bernal⁹, J. Bravo¹⁰, B. Revollo¹¹, J. Macias¹², J.M. Tiraboschi¹³, R. Montejano¹⁴, C. Amador¹⁵, M. Torralba¹⁶, D. Merino¹⁷, V. Diaz-Brito¹⁸, M.J. Galindo¹⁹, S. Ferrá²⁰, A. Villoslada²¹, J.E. Losa²², F.J. Fanjul²³, J. Perez-Stachowski²⁴, J. Peraire²⁵, J. Portilla²⁶, S. de la Fuente²⁷, C. Dueñas²⁸, M.J. Vazquez²⁹, S. Di Gregorio³⁰, E. Manzanares³¹, P. Gil³¹, M. de Miguel³¹, B. Alejos³², E. Martinez²

¹Hospital Universitario Infanta Leonor, Madrid, Spain,

²Hospital Clínic, Infectious Diseases, Barcelona, Spain,

³Hospital General Universitario, Elche, Spain, ⁴Hospital

Universitario de la Princesa, Madrid, Spain, ⁵Hospital

Clínico Universitario Lozano Blesa, Zaragoza, Spain,

⁶Hospital de la Santa Creu i Sant Pau, Barcelona, Spain,

⁷Hospital Universitari Vall d'Hebron, Barcelona, Spain,

⁸Hospital del Mar, Barcelona, Spain, ⁹Hospital Reina Sofía,

Murcia, Spain, ¹⁰Hospital Morales Meseguer, Murcia, Spain,

¹¹Hospital Universitari Germans Trias i Pujol, Badalona,

Spain, ¹²Hospital Universitario Virgen de Valme, Sevilla,

Spain, ¹³Hospital Universitario de Bellvitge, L'Hospitalet de

Llobregat, Spain, ¹⁴Hospital Universitario La Paz, Madrid,

Spain, ¹⁵Hospital Marina Baixa, Villajoyosa, Spain, ¹⁶Hospital

Universitario, Guadalajara, Spain, ¹⁷Hospital Juan Ramon

Jimenez, Huelva, Spain, ¹⁸Parc Sanitari Sant Joan de Deu,

Sant Boi de Llobregat, Spain, ¹⁹Hospital Clínico Universitario,

Valencia, Spain, ²⁰Hospital Universitario Torrecárdenas,

Almería, Spain, ²¹Hospital Universitario Son Llatzer, Palma

de Mallorca, Spain, ²²Hospital Universitario Fundación

Alcorcón, Alcorcón, Spain, ²³Hospital Universitario Son

Espases, Palma de Mallorca, Spain, ²⁴Hospital Costa del

Sol, Marbella, Spain, ²⁵Hospital Universitari Joan XXIII,

Tarragona, Spain, ²⁶Hospital General Universitario Dr.

Balmis, Alicante, Spain, ²⁷Hospital Universitario Puerta de

Hierro-Majadahonda, Majadahonda, Spain, ²⁸Hospital

Clínico Universitario, Valladolid, Spain, ²⁹ViiV Healthcare,

Tres Cantos, Spain, ³⁰CP Endocrinología i Nutrició S.L.,

Barcelona, Spain, ³¹Fundación SEIMC-GeSIDA, Madrid, Spain,

³²Independent researcher, Madrid, Spain

Background: DTG/3TC and BIC/FTC/TAF are preferred regimens in major guidelines, but there are no fully powered trials comparing between them.

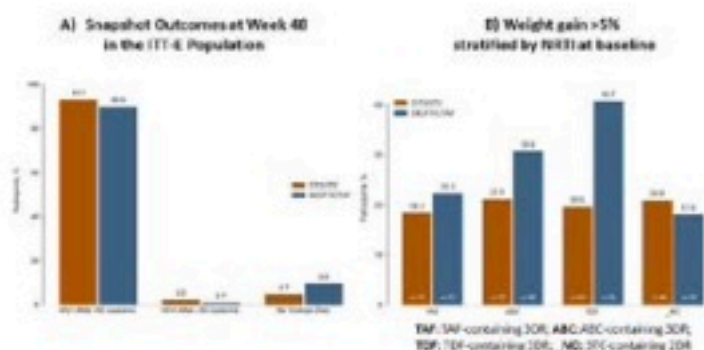
Methods: PASO-DOBLE (ClinicalTrials.gov NCT04884139) is a randomized, open-label trial conducted at 30 sites throughout Spain. Virologically suppressed PWH on reg-

imens containing ≥ 1 pill/day, boosters, or drugs with cumulative toxicity such as efavirenz or TDF were eligible. Participants were randomized (1:1) to switch stratifying by TAF in the regimen discontinued and sex. Primary endpoint was the proportion of PWH with RNA ≥ 50 copies/mL at 48 weeks (FDA snapshot, 4% non-inferiority margin) in the exposed intention-to-treat population. Weight changes were also evaluated.

Results: Between 14-July-2021 and 24-March-2023, 553 PWH initiated DTG/3TC (n=277) or BIC/FTC/TAF (n=276), including 155 (28%) with TAF in the regimen discontinued and 147 (27%) women. At 48 weeks, DTG/3TC was non-inferior to BIC/FTC/TAF [risk difference between DTG/3TC (2.2%) minus BIC/FTC/TAF (0.7%) 1.4%, 95%CI -0.5 to 3.4] (Figure A). HIV RNA levels were low (≤ 282 copies/mL) in those showing detectable viral load.

Mean adjusted weight increased significantly more with BIC/FTC/TAF (1.81kg, 95%CI 1.28-2.34) than with DTG/3TC (0.89kg, 95%CI 0.37-1.41) [difference 0.92kg, 95%CI 0.17-1.66]. The proportion of participants with weight gain $>5\%$ at 48 weeks was 29.9% for BIC/FTC/TAF vs. 20% for DTG/3TC (adjusted OR 1.81, 95%CI 1.19-2.76).

While proportions of PWH experiencing $>5\%$ weight gain with DTG/3TC were similar irrespective of the nucleos(t)ide reverse transcriptase inhibitor (NRTI) backbone discontinued, proportions of PWH experiencing $>5\%$ weight gain with BIC/FTC/TAF were 50% or 100% higher than those with DTG/3TC when switching from abacavir or TDF (Figure B). Weight change in women (OR 1.131, 95% CI: 0.700-1.826) didn't differ from that in men. There were few discontinuations (DTG/3TC=1, 0.4%; BIC/FTC/TAF=2, 0.7%) due to adverse events.



Conclusions: Switching to DTG/3TC demonstrated non-inferior efficacy and resulted in less weight gain than switching to BIC/FTC/TAF at 48 weeks.