

POSTER PRESENTATION

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Long-term outcomes of switching to fixed-dose abacavir/lamivudine (ABC/3TC) or tenofovir/emtricitabine (TDF/FTC): 3-year results of the BICOMBO study

E Martínez¹, JA Arranz², D Podzamczar³, M Lonca¹, J Sanz², P Barragán³, H Knobel⁴, E Ribera⁵, F Gutierrez⁶, S Valero⁷, B Clotet⁸, D Dalmau⁹, F Segura¹⁰, JR Arribas¹¹, P Barrufet¹², I Santos¹³, A Payeras¹⁴, E de Lazzari¹, J Pich¹, J Gatell^{1*}

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Background

Once-daily fixed-dose combinations ABC/3TC and TDF/FTC are the preferred backbones in Europe [1]. Long-term (>2 years) efficacy and safety of these compounds in simplification strategies are unknown.

Methods

333 HIV-1-infected adults on 3TC-containing triple regimens with <200 copies/mL for at least 6 months had their NRTI backbone randomly switched to either ABC/3TC or TDF/FTC. Pre-planned results at 1 year have been already published [2]. Treatment failure (defined as virological failure, discontinuation of study therapy, withdrawal of consent, lost to follow-up, progression to AIDS, or death), virological failure (defined as confirmed plasma HIV-1 RNA >200 copies/mL), adverse events, and changes in CD4 cells, fasting plasma lipids, glomerular filtration rate (GFR) (Cockcroft-Gault), and transaminases at 3 years were compared between arms.

Results

Treatment failure increased from 32 (19%) to 58 (35%) patients on ABC/3TC and from 22 (13%) to 61 (37%) patients on TDF/FTC at 1 and 3 years, respectively (HR for ABC/3TC treatment failure at 3 years 0.99, 95% CI 0.69-1.41). The most common reasons for treatment failure at 3 years in both arms were lost to follow-up/

withdrawal of consent (68 patients, 20%) or discontinuation of study drugs for reasons other than adverse events (15 patients, 5%). Total discontinuations due to adverse events increased from 17 at 1-year to 18 patients at 3-years on ABC/3TC and from 9 at 1-year to 10 patients at 3-years on TDF/FTC. Total virological failures increased from 4 at 1-year to 6 patients at 3-years on ABC/3TC while no patient on TDF/FTC developed virological failure at 1-year and through 3-years (HR for ABC/3TC virological failure at 3 years 3.59, 95% CI 0.77-6.42). Change from baseline (mg/dL) in triglycerides (+1 vs -29, P=0.008), total cholesterol (+12 vs -12, P<0.001), LDL-cholesterol (+1 vs -1, P<0.001), and HDL-cholesterol (+3 vs -2, P<0.001) were increased in patients on ABC/3TC compared with decreases in patients on TDF/FTC, although total-to-HDL cholesterol ratio remained almost identical in both arms. There were no significant changes in GFR or transaminases in each arm at 3-years.

Conclusion

From the 1-year analysis, we observed two additional virological failures in patients on ABC/3TC; there were no virological failures in patients on TDF/FTC over 3 years. Through 3 years long-term safety/tolerability was very good. Differential lipid effects between arms were maintained at 3 years.

¹Hospital Clínic-IDIBAPS, Barcelona, Spain
Full list of author information is available at the end of the article

Author details

¹Hospital Clínic-IDIBAPS, Barcelona, Spain. ²Hospital Príncipe de Asturias, Alcala de Henares, Spain. ³Hospital de Bellvitge, L'Hospitalet de Llobregat, Spain. ⁴Hospital del Mar, Barcelona, Spain. ⁵Hospital de Vall d'Hebron, Barcelona, Spain. ⁶Hospital Universitario de Elche, Elche, Spain. ⁷Hospital Sant Jaume, Calella, Spain. ⁸Hospital Germans Trias i Pujol, Badalona, Spain. ⁹Hospital de Mutua de Terrassa, Terrassa, Spain. ¹⁰Hospital Parc Tauli, Sabadell, Spain. ¹¹Hospital La Paz, Madrid, Spain. ¹²Hospital de Mataro, Mataro, Spain. ¹³Hospital Universitario de La Princesa, Madrid, Spain. ¹⁴Hospital Son Llatzer, Palma de Mallorca, Spain.

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