Background
- Dyslipidaemia contributes to cardiovascular risk in HIV patients.
- Comparative studies suggest tenofovir DF based regimens have a favourable lipid profile relative to abacavir based regimens.
- We sought to investigate if such changes are seen in hypercholesterolaemic patients when switched from ABC/3TC + LPV/r to TDF/FTC + LPV/r.

Objectives
- Primary Objective
  - Determine whether switching from ABC/3TC to TDF/FTC while maintaining LPV/r leads to a reduction in fasting total cholesterol (TC) after 12 weeks
- Secondary Objectives
  - Evaluation of fasting metabolic parameters (LDL, triglycerides, cholesterol ratio)
  - Evaluation of changes in the 10-year risk for coronary heart disease (CHD) outcomes as measured by Framingham Risk Score
  - Evaluation of efficacy and safety

Methods
- Virologically stable subjects on ABC/3TC + LPV/r for ≥6 months, with HIV RNA <50 copies/ml were randomized (1:1) to continue ABC/3TC+LPV/r or switch to TDF/FTC+LPV/r.
- Analyses assessed changes in fasting metabolic parameters and 10-year risk for CHD (Framingham equation).
- Numbers and percentages of subjects with CHD risk in the categories of <10, 10% to 20%, and >20% were summarized at Baseline and Week 12.
- All laboratory evaluations were done in a central lab.
- This open-label, 2-arm controlled study was conducted in accordance with GCP.

Results

Table 1. Baseline Characteristics*

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>ABC/3TC (n=43)</th>
<th>TDF/FTC (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age in years (IQR)</td>
<td>48 (38, 51)</td>
<td>43 (38, 48)</td>
</tr>
<tr>
<td>Gender male n (%)</td>
<td>35 (81.4%)</td>
<td>31 (73.8%)</td>
</tr>
<tr>
<td>Median BMI (kg/m²)</td>
<td>25.2 (21.1, 27.6)</td>
<td>25.0 (22.5, 30.7)</td>
</tr>
<tr>
<td>Median total cholesterol (mmol/L)</td>
<td>6.3 (5.1, 7.6)</td>
<td>6.3 (5.7, 7.06)</td>
</tr>
</tbody>
</table>

Conclusions
- Switching from ABC/3TC (Kivexa) to TDF/FTC (Truvada) in patients with raised cholesterol – significantly and quickly reduces lipid parameters
- Reduces 10 year estimated CHD risk
- Maintains virologic control

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