Background

• Dyslipidaemia contributes to CV risk in HIV infection
• Tenorin DF-based regimens may have a favourable lipid profile relative to alternative-based regimens
• We investigated changes in fasting total cholesterol (TC) in hypercholesterolaemic participants switching to the single tablet regimens of Atripla® (KIV) vs efavirenz (KIV-EXV)

Objectives

• Primary Objective
  Determine whether switching from Kivexa® + Efavirenz to QD Atripla leads to a reduction in fasting total cholesterol in 12 weeks
• Secondary Objectives
  – Evaluation of fasting metabolic parameters (e.g., LDL, HDL, triglycerides, non-HDL cholesterol and triglycerides)
  – Evaluation of efficacy and safety
  – Evaluation of changes in the 10-year risk for coronary heart disease outcomes as measured by Framingham risk score

Methods

• 159 participants stable on KVX + Efavirenz for ≥6 months
• Entry criteria
  – Undetectable viral load (mv) for 6 months with HIV RNA < 50 copies/ml, for ≥2 months and cholesterol ≤5.2 mmol/L randomised to switch to ATR or continue KIV-efavirenz
• At Week 12, participants randomised to KIV-efavirenz were switched to ATR and all participants continued through to Week 24
• The primary endpoint was in change from baseline to Week 12
• Fasting lipid parameters were assessed using NCEP thresholds

Results

Table 1. Baseline Participant Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Atripla</th>
<th>Kivexa + Efavirenz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Participants</td>
<td>78</td>
<td>78</td>
</tr>
<tr>
<td>Median age in yrs (Q3)</td>
<td>42 (40, 45)</td>
<td>44 (40, 50)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>45 (57.0%)</td>
<td>48 (61.5%)</td>
</tr>
<tr>
<td>Black</td>
<td>29 (36.7%)</td>
<td>27 (34.6%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (3.9%)</td>
<td>2 (2.6%)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>57 (73.0%)</td>
<td>56 (72.2%)</td>
</tr>
<tr>
<td>Female</td>
<td>21 (27.0%)</td>
<td>22 (27.8%)</td>
</tr>
<tr>
<td>HIV RNA &lt; 50 copies/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤50 copies/mL</td>
<td>75% (98.9%)</td>
<td>79% (98.9%)</td>
</tr>
<tr>
<td>&gt;400 copies/mL</td>
<td>5% (11.1%)</td>
<td>2% (2.6%)</td>
</tr>
<tr>
<td>Median BMI (kg/m²) (IQR)</td>
<td>25.7 (23.7, 29.3)</td>
<td>25.5 (23.7, 28.8)</td>
</tr>
</tbody>
</table>

Table 2. Patient Disposition at Week 12

<table>
<thead>
<tr>
<th>N (%)</th>
<th>Atripla (N=78)</th>
<th>Kivexa + Efavirenz (N=78)</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Participants Completing 12 Weeks of Study</td>
<td>78 (96.3%)</td>
<td>78 (94.9%)</td>
</tr>
<tr>
<td>Treatment Discontinuation (Prior to Week 12)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Event</td>
<td>1 (1.3%)</td>
<td>2 (2.5%)</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Protocol Violation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Withdrawal Consent</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Investigator's Decision</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Conclusions

• Switching to Atripla® from Kivexa® + Efavirenz significantly improved atherogenic lipid parameters towards desirable levels (per NCEP guidelines)
• Viral suppression was maintained
• Replacement of Kivexa® + Efavirenz with Atripla may be part of an appropriate management approach in hypercholesterolaemic patients

Acknowledgements

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References