**Introduction**

- All currently “preferred” and “recommended” regimens for antiretroviral-naïve patients include two nucleoside reverse transcriptase inhibitors (NRTIs).
- NRTI-sparing regimens may prevent NRTI associated long-term toxicities such as tenofovir and bone toxicities.
- Data on the effectiveness of non NRTI containing combinations is limited.

**Methods**

**Study Objectives / Endpoints**

- Primary: Proportion of patients with HIV RNA < 50 c/mL at week 24
- Secondary: Change from baseline in CD4 cell counts at weeks 24 & 48
- Proportion of patients with HIV RNA < 50 c/mL at week 48
- Changes through weeks 24 & 48:
  - Lipid profile
  - Insulin resistance
  - Bone density
  - Body fat changes

**Results**

**Table 1. Baseline characteristics**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>RAL (n=40)</th>
<th>TVD (n=43)</th>
<th>Total (n=83)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Age (years)</td>
<td>43.8</td>
<td>50.1</td>
<td>41.9</td>
</tr>
<tr>
<td>Male Gender (%)</td>
<td>90%</td>
<td>90%</td>
<td>90%</td>
</tr>
<tr>
<td>Race (AA/Non- AA: %)</td>
<td>40/29/26</td>
<td>51/23/26</td>
<td>48/26/26</td>
</tr>
<tr>
<td>BL Median Log10 HIV RNA (c/mL)</td>
<td>4.69</td>
<td>4.92</td>
<td>4.81</td>
</tr>
<tr>
<td>BL Median CD4 (cells/mm³)</td>
<td>249</td>
<td>201</td>
<td>223</td>
</tr>
</tbody>
</table>

**Table 2. Changes in lipids.** Tenofovir was associated with a smaller increase in Total Cholesterol.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean Baseline Values</th>
<th>Mean % Change From Baseline</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC (mg/dL)</td>
<td>159 ± 44</td>
<td>+8.4%</td>
<td>0.06</td>
</tr>
<tr>
<td>LDL (mg/dL)</td>
<td>94 ± 26</td>
<td>+19.4%</td>
<td>0.001</td>
</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>54 ± 7</td>
<td>-18.2%</td>
<td>0.001</td>
</tr>
<tr>
<td>TG (mg/dL)</td>
<td>142 ± 39</td>
<td>+20.7%</td>
<td>0.001</td>
</tr>
</tbody>
</table>

**Results (cont)**

- Similar CD4 changes at Week 48: 199 for RAL and 216 for TDF/FTC (p=0.631)
- Similar % VL<200 copies/mL: 72.5% and 86.6% for RAL and TDF/FTC (p=0.175); but % VL<48 was lower for RAL 62.5% vs.

**Figure 4. Bone and body composition changes.** Patients in the tenofovir containing arm had significantly more bone loss and similar body composition changes when their markers of bone formation and destruction indicate a higher bone turnover.

**Figure 5. Changes in markers of bone formation and destruction correlate with changes in BMD.**

**Conclusions**

- Patients on the NRTI-sparing regimen RAL + DRV/RTV achieved faster virological suppression but over 48 weeks had more treatment discontinuations and less virological suppression. Our findings are consistent with the ones observed in ACTG 5262 and could be due to the twice a day administration or unknown PK interactions.
- Patients in the TVD arm had similar changes in total cholesterol.
- Patients taking RAL had lower bone turnover and less bone loss than the ones on tenofovir. However, this was not explained by differential changes in inflammatory markers. Nucleoside-sparing regimens might be associated with improved bone health.
- Early Changes in bone turnover at week 16 were predictive of changes in bone density at week 48.

**Acknowledgments**

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