INTRODUCTION

Several recent studies have highlighted the importance of cardiovascular issues in HIV-infected individuals. This study added TDF to a stable antiretroviral regimen to evaluate the effect of TDF on lipid parameters. In order to confirm our results, 2 sample t-tests were used for 1) treatment effect adjusted for baseline and 2) treatment-by-week interaction. 

RANDomization

ACTG A5206 was a double-blind, randomized, placebo-controlled, crossover pilot study of increasing doses of TDF on lipid parameters in HIV-infected subjects. The study was designed to test the hypothesis that the addition of TDF to existing virologically-suppressed ART regimens improves lipid parameters, supporting the use of TDF in combination with other ART. 

ACKNOWLEDGMENTS

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REFERENCES

The authors declare no competing interests. This study was supported in part by the National Institutes of Health, Department of Health and Human Services.

SUMMARY AND CONCLUSIONS

The addition of TDF to virologically-suppressed ART regimens required lipid parameters, supporting an independent lipid-lowering effect of TDF. The mechanism of the lipid-lowering effect and potential rebound effect of increased TG with discontinuation of TDF treatment were observed. 

RESULTS

- 14 subjects enrolled; 12 (86%) were men, 8 (57%) were black, and 8 (57%) were Hispanic.
- Subjects were randomized to TDF or placebo, followed by the opposite sequence.
- One subject from each arm was lost to follow-up (1 started lipodystrophy agents, 1 wished to DE medication).
- Did not have week 28 lipid level data from 2 subject (1 did not have week 28 fasting lipids; 1 started lipid-lowering agent in violation of protocol). 

Table 1 - Median changes lipid parameters over TDF treatment period in comparison to placebo treatment period.

<table>
<thead>
<tr>
<th>Lipid Parameter</th>
<th>Placebo Median (IQR)</th>
<th>TDF Median (IQR)</th>
<th>% ∆ Placebo Median (IQR)</th>
<th>% ∆ TDF Median (IQR)</th>
<th>Hodges-Lehman estimate of the median paired difference (∆ (%∆) TDF – ∆ (%∆) Placebo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HDL-C</td>
<td>45 (39, 53)</td>
<td>47 (41, 55)</td>
<td>-2% (-7%, 5%)</td>
<td>-16% (-26%, -4%)</td>
<td>-13% (-34%, 15%)</td>
</tr>
<tr>
<td>LDL-C</td>
<td>119 (107, 133)</td>
<td>117 (105, 129)</td>
<td>4% (-10%, 13%)</td>
<td>6% (-8%, 18%)</td>
<td>3% (-10%, 11%)</td>
</tr>
<tr>
<td>Total-C</td>
<td>175 (159, 188)</td>
<td>172 (157, 187)</td>
<td>-2% (-7%, 5%)</td>
<td>-8% (-24%, 3%)</td>
<td>-1% (-5%, 11%)</td>
</tr>
<tr>
<td>Non-HDL-C</td>
<td>121 (113, 129)</td>
<td>113 (107, 121)</td>
<td>4% (-10%, 13%)</td>
<td>-8% (-24%, 3%)</td>
<td>-3% (-10%, 11%)</td>
</tr>
<tr>
<td>TG</td>
<td>117 (91, 176)</td>
<td>114 (76, 164)</td>
<td>3% (-10%, 13%)</td>
<td>-5% (-8%, 11%)</td>
<td>-2% (-9%, 9%)</td>
</tr>
</tbody>
</table>

P-values:
aOne-Sided Wilcoxon Signed Rank test; 
bOne-Sided Hodges-Lehman test; 
cTwo-Sided Wilcoxon Signed Rank test; 
dTwo-Sided Hodges-Lehman test; 
eOne-Sided Hodges-Lehman test; 
fTwo-Sided Hodges-Lehman test; 
gOne-Sided Wilcoxon Signed Rank test; 
hTwo-Sided Wilcoxon Signed Rank test; 
iOne-Sided Wilcoxon Signed Rank test; 
jTwo-Sided Wilcoxon Signed Rank test.

Figure 2 - Median changes in lipid parameters by week

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The addition of TDF to virologically-suppressed ART regimens required lipid parameters, supporting an independent lipid-lowering effect of TDF. The mechanism of the lipid-lowering effect and potential rebound effect of increased TG with discontinuation of TDF treatment were observed.

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