BACKGROUND

The ACTG 5257 clinical trial included patients with HIV-1 infection, commonly used treatments include the following:

- Raltegravir (RAL) 400 mg twice daily
- Atazanavir/ritonavir (ATV/r) 300 mg/100 mg once daily
- Darunavir/ritonavir (DRV/r) 800 mg/100 mg once daily

The ACTG 5257 clinical trial is a head-to-head comparison evaluating the efficacy and tolerability of these treatments when used in combination with emtricitabine/tenofovir DF (FTC/TDF) (200 mg/300 mg once daily, among treatment-naive adults with HIV-1 infection in the United States). At 56 weeks of follow-up, the RAL regimen exhibited favorable efficacy and safety results compared to the ATV/r and DRV/r regimens.

OBJECTIVE

The objective of this study was to estimate the HIV treatment costs associated with the three antiretroviral regimens examined in the ACTG 5257 clinical trial for the US.

METHODS

Model Overview

The costs analysis followed a cohort of treatment-naive individuals with HIV-1 infection in the US from baseline through 56 weeks as they progressed through treatment in the ACTG 5257 clinical trial. As individuals progressed, the model tracked the costs incurred and estimated per-person costs by category and in aggregate for each first-line regimen.

The first-line regimens analyzed and the modeled costs outcomes for each are shown in Figure 1.

Table 1 ACTG 5257 Clinical Trial Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Pooled</th>
<th>Female</th>
<th>HIV RNA ≥ 100,000 copies</th>
<th>Maximum CD4 count (cells/µL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>100%</td>
<td>98%</td>
<td>99%</td>
<td>100%</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>27</td>
<td>28</td>
<td>27</td>
<td>27</td>
</tr>
<tr>
<td>Female</td>
<td>22.8%</td>
<td>22.9%</td>
<td>22.4%</td>
<td>22.9%</td>
</tr>
<tr>
<td>HIV RNA ≥ 100,000 copies</td>
<td>65.9%</td>
<td>66.7%</td>
<td>65.3%</td>
<td>66.2%</td>
</tr>
<tr>
<td>Maximum CD4 count (cells/µL)</td>
<td>115%</td>
<td>113%</td>
<td>114%</td>
<td>115%</td>
</tr>
<tr>
<td>&lt; 200</td>
<td>11%</td>
<td>12%</td>
<td>10%</td>
<td>11%</td>
</tr>
<tr>
<td>200-349</td>
<td>16%</td>
<td>15%</td>
<td>17%</td>
<td>16%</td>
</tr>
<tr>
<td>350-499</td>
<td>25%</td>
<td>24%</td>
<td>25%</td>
<td>24%</td>
</tr>
<tr>
<td>500-699</td>
<td>16%</td>
<td>15%</td>
<td>17%</td>
<td>16%</td>
</tr>
<tr>
<td>≥ 700</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
</tr>
</tbody>
</table>

*Data presented as n or n (%), unless otherwise noted.

Table 2 Adverse Event Incidence and Costs

<table>
<thead>
<tr>
<th>Adverse Event Category</th>
<th>Grade 2/3 Incidence</th>
<th>Cost Per Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipid abnormalities</td>
<td>1.4%</td>
<td>$748</td>
</tr>
<tr>
<td>Gastrointestinal signs and symptoms, nausea and vomiting, and defaecation conditions</td>
<td>2.0%</td>
<td>$1,214</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>2.0%</td>
<td>$1,214</td>
</tr>
<tr>
<td>Nausea</td>
<td>4.5%</td>
<td>$1,044</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>2.0%</td>
<td>$2,643</td>
</tr>
</tbody>
</table>

*Costs were inflated from 2006 to 2014 US dollars.

Figure 3. Substitution Regimens Following Discontinuation of Study Regimen

The model was developed as a decision analytic model to evaluate and compare the costs among the three antiretroviral regimens in treatment-naive adults with HIV-1 infection in the United States. The model included costs and efficacy data from the ACTG 5257 clinical trial and did not incorporate other costs or clinical endpoints.

RESULTS

- RAL had the lowest per-person total cost after 56 weeks of treatment compared with DRV/r and ATV/r when each was used in combination with FTC/TDF.

- Model results were robust in scenario and sensitivity analyses.

- RAL had the lowest per-person total cost in all scenarios tested (alternate trial endpoint for regimen discontinuation, shorter time horizon, no discounting, without adverse event costs, without HIV care costs). 100% probability, sensitivity analysis (PSA) found RAL to have the lowest total per-person cost (Figure 4).

- ATV/r had the widest variability in per-person total costs due to the high incidence of hospitalization, investigation events and the substantial uncertainty in the associated cost per event (Figure 4).

- The 95% confidence interval for the total per-person cost for RAL in the PSA did not overlap with the confidence interval for either of the two comparator regimens (Figure 5).

Figure 5. Distribution of PSA Results

The model was developed as a decision analytic model to evaluate and compare the costs among the three antiretroviral regimens in treatment-naive adults with HIV-1 infection in the United States.

LIMITATIONS

- This analysis was limited to the first-line regimens included in the ACTG 5257 clinical trial and did not incorporate other common first-line regimens.

- Since clinical trial participants typically achieve very high levels of adherence, the modeled efficacy results may be better than those observed in real-world clinical practice.

- Cost outcomes were estimated through 56 weeks only; potential long-term benefits of RAL were not captured.

- Adverse event and HIV care cost data were somewhat dated but were the most recent available.

DISCUSSION AND CONCLUSIONS

- RAL has the lowest total per-person 96-week cost when compared with ATV/r and DRV/r for treatment-naive adults with HIV-1 infection in the US.

- These results were found to be robust in sensitivity and scenario analyses.

- This economic evidence complements the known clinical benefits of RAL as reported in the ACTG 5257 clinical trial.

REFERENCES


6. The ACTG 5257 trial was funded by Merck & Co., Inc., Kenilworth, NJ, United States and RTI Health Solutions, Research Triangle Park, NC 27709.

CONTACT INFORMATION

Ashley E. Davis,1 Anita J. Brogan,1 Bridgett Goodwin2
1 RTI Health Solutions, Research Triangle Park, NC, United States; 2 Merck & Co., Inc., Kenilworth, NJ, United States

Presented at: ISPOR 21st Annual International Meeting, May 21-25, 2016, Washington, DC, United States