Rilpivirine-TDF-FTC in HIV-HCV Coinfected Patients

hEPAtic Study
## Rilpivirine-TDF-FTC in HIV-HCV Coinfected Patients

### hEPAtic: Design

#### Study Design: hEPAtic STUDY

- **Background**: Retrospective, case-control study to evaluate the hepatic safety (as measured by frequency of transaminase and total bilirubin elevations) of rilpivirine-tenofovir DF-emtricitabine once daily in HIV-HCV-coinfected patients.

- **Inclusion Criteria (n = 519)**
  - Age >18 years
  - Chronic HCV (detectable HCV RNA)
  - Starting new antiretroviral (ART) regimen

- **Treatment Arms**
  - EPA Group: Rilpivirine-tenofovir DF-emtricitabine
  - Control Group: Other new antiretroviral regimen

#### EPA group

- **RPV-TDF-FTC**
  - (n = 173)

#### Control Group

- **Other ART Regimen**
  - (n = 346)

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EPA = rilpivirine-tenofovir DF-emtricitabine (*Complera*)

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## Newly introduced antiretroviral therapy (ART) in the control group (n=346)

<table>
<thead>
<tr>
<th>Antiretroviral Drug</th>
<th>Initiated ART (%)</th>
<th>Antiretroviral Drug</th>
<th>Initiated ART (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tenofovir DF-emtricitabine</td>
<td>21.7</td>
<td>Efavirenz</td>
<td>9.5</td>
</tr>
<tr>
<td>Abacavir-lamivudine</td>
<td>12.4</td>
<td>Nevirapine</td>
<td>2.9</td>
</tr>
<tr>
<td>Other NRTI combinations</td>
<td>11</td>
<td>Etravirine</td>
<td>8.7</td>
</tr>
<tr>
<td>Lopinavir/ritonavir</td>
<td>4.3</td>
<td>Raltegravir</td>
<td>13</td>
</tr>
<tr>
<td>Atazanavir/ritonavir</td>
<td>13.9</td>
<td>Maraviroc</td>
<td>6.9</td>
</tr>
<tr>
<td>Darunavir/ritonavir</td>
<td>32.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Frequency of Severe Hepatic Toxicity

<table>
<thead>
<tr>
<th>Marker of Severe Hepatic Toxicity</th>
<th>RPV-TDF-FTC</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 3-4 Transaminase Elevations (TE)</td>
<td>2/173 (1.2%)</td>
<td>11/346 (3.2%)</td>
</tr>
<tr>
<td>Grade 4 Total Bilirubin Elevations (TBE)</td>
<td>1/173 (0.6%)</td>
<td>8/346 (2.3%)</td>
</tr>
</tbody>
</table>

Grade 3 TE = ALT or AST 5-10x ULN; Grade 4 TE = ALT or AST > 10x ULN; Grade 4 TBE: total bilirubin ≥ 5 mg/dL

Rilpivirine-TDF-FTC in HIV-HCV-Coinfected Patients

**hEPAtic: Result**

Discontinuation, Decompensation, and Death

<table>
<thead>
<tr>
<th>Event</th>
<th>RPV-TDF-FTC (%)</th>
<th>Control group (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinuation for any Adverse Event</td>
<td>8.0</td>
<td>0.6</td>
</tr>
<tr>
<td>Hepatic Decompensation</td>
<td>5.2</td>
<td>1.7</td>
</tr>
<tr>
<td>Death due to Hepatic Event</td>
<td>0.2</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Rilpivirine-TDF-FTC in HIV-HCV-Coinfected Patients
hEPAtic: Result

Grade 3-4 Transaminase Elevation, by Degree of Hepatic Fibrosis

Rilpivirine-FTC-TDF in HIV-HCV Coinfected Patients

hEPAtic: Result

Grade 3-4 Transaminase Elevation, by Presence of Cirrhosis

**Conclusion**: “The frequency of severe liver toxicity in HIV/HCV-coinfected subjects receiving EPA under real-life conditions is very low, TE were generally mild and did not lead to drug discontinuation. All these data suggest that EPA can be safely used in this particular subpopulation.”

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