Efficacy of Rilpivirine-based Regimens as Switch Therapy in HIV-infected Patients with Complete Virological Suppression: A Randomized Controlled Trial

Porkaew Petchkum, M.D.1, Somnuek Sungkanuparph, M.D.2, Sasisopin Kiertiburanakul, M.D., M.H.S.1, Angsana Phuphuakrat, M.D., Ph.D.1

1Division of Infectious Diseases, Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand
2Chakri Naruebodindra Medical Institute, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Samut Prakan, Thailand

Contact e-mail: bimpetchkum@gmail.com

Once daily dose antiretroviral therapy (ART) regimens improve adherence and treatment satisfaction
Nevirapine (NVP)-based ART remains to be used in some patients despite its twice daily dosing
Switching to rilpivirine (RPV)-based regimens is an alternative but there has been limited experience with RPV

Background

To compare efficacy of RPV-based regimens as switch therapy to NVP-based regimens continuation in HIV-infected patients with viral suppression
To observe changes in CD4 cell counts and lipid profiles from the baseline

Objectives

Patients and Methods

A randomized controlled, non-inferiority study
HIV-infected patients who visited the outpatient clinic at Ramathibodi Hospital
December 2016 to October 2017
Received NVP-based regimens for >6 months and had undetectable viral load
Intention-to-treat and per-protocol analyses for primary analysis

Results

109 HIV-infected patients who had been treated with TDF/FTC + NVP or TDF + 3TC + NVP
3 Excluded
1 withdraw consent
1 GFR <60 ml/min
1 psychiatric disorder
55 continued NVP-based regimens
Discontinued treatment
2 dead
53 treatment ongoing
51 switched to RPV-based regimens
Discontinued treatment
1 AE discontinued RPV
50 treatment ongoing

106 enrolled and randomized

55 included in intention-to-treat analysis at week 24
51 included in intention-to-treat analysis at week 24

Conclusions

Switching from NVP to RPV can maintain virological suppression and decreases total cholesterol at week 24
In virologically suppressed HIV-infected patients on treatment with NVP-based regimens, once daily RPV-based regimens are an alternative switch option

Acknowledgement

This study was supported by grants from Faculty of Medicine Ramathibodi Hospital, Mahidol University and the Thai AIDS Society

Table 1. Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Continuation Arm (group A)</th>
<th>Switch Arm (group B)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>29 (52.7)</td>
<td>26 (47.3)</td>
<td>0.857</td>
</tr>
<tr>
<td>Mean (SD) age, years</td>
<td>50.0 (9.6)</td>
<td>48.2 (8.9)</td>
<td>0.325</td>
</tr>
<tr>
<td>Mean (SD) body weight, kg</td>
<td>58.4 (10.6)</td>
<td>58.8 (9.9)</td>
<td>0.849</td>
</tr>
<tr>
<td>Median (IQR) CD4 cell count, cells/mm³</td>
<td>552 (434-733)</td>
<td>563 (457-727)</td>
<td>0.912</td>
</tr>
<tr>
<td>Mean (SD) duration of ART, years</td>
<td>10.8 (4.3)</td>
<td>11.0 (4.0)</td>
<td>0.877</td>
</tr>
<tr>
<td>Prior NRTI and NNRTI use, n (%)</td>
<td>26 (47.3)</td>
<td>23 (45.1)</td>
<td>0.662</td>
</tr>
<tr>
<td>Stavudine</td>
<td>19 (34.6)</td>
<td>22 (43.1)</td>
<td></td>
</tr>
<tr>
<td>Zidovudine</td>
<td>7 (12.7)</td>
<td>5 (9.2)</td>
<td></td>
</tr>
<tr>
<td>Underlying diseases, n (%)</td>
<td>35 (63.6)</td>
<td>41 (80.4)</td>
<td>0.053</td>
</tr>
<tr>
<td>No underlying diseases</td>
<td>2 (3.6)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>11 (20.0)</td>
<td>2 (3.9)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>2 (3.6)</td>
<td>4 (7.8)</td>
<td></td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>5 (9.1)</td>
<td>5 (9.1)</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1. Study screening, enrollment, and follow-up through week 24

Figure 2. Proportion of virologic success and CD4 cell count outcomes at week 24

Figure 3. Mean lipid changes at week 24

* 0.001

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