Virological suppression and weight gain in children in Europe on dolutegravir compared to protease inhibitors: a propensity score analysis


Methods

• Randomised controlled trials (RCTs) are the gold standard for assessing the effects of an intervention. Propensity scores (PS) offer a method to estimate treatment effect in non-randomised data and can be used to match individuals who are 'treated' to similar 'untreated' individuals.

• Viral suppression, zBMI and weight change on DTG and PI were compared using PS matching among those ART-experienced at drug start (insufficient numbers ART naïve).

• PS were based on characteristics at start of DTG/PI: age, sex, ethnicity, time since ART initiation, history of treatment failure, prior AIDS event, CD4 and BMI-for-age z-score.

Results: Patient characteristics and unadjusted outcomes on DTG and PIs

Table 1: Characteristics of CLWHIV on DTG/PI+2NRTIs

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>DTG (n=938)</th>
<th>PI (n=1582)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%) Median (IQR)</td>
<td>Male sex 294 (46%)</td>
<td>431 (46%)</td>
</tr>
<tr>
<td>Race ethnicity</td>
<td>Black 900 (95%)</td>
<td>664 (78%)</td>
</tr>
<tr>
<td>Age (years) at ART start</td>
<td>4.4 (9.7)</td>
<td>5.6 (10.0)</td>
</tr>
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</table>

Characteristics of CLWHIV on DTG (Fig 1A/8).

• Overall, 1582 CLWHIV were included; 644 on DTG and 938 on PI (Tables 1 & 2).

• CLWHIV on PI had lower CD4 counts, were more likely to have failed treatment in the past (Table 1) and had lower zBMI (Table 2) than those on DTG; these differences disappeared after matching by PS.

• Among those on PI, 51% were on darunavir, 25% atazanavir and 24% lopinavir.

• Overall suppression was higher on DTG than PI (Fig 1A/8).

• Among CLWHIV who were ART-experienced and unsuppressed at DTG/PI start <80% on DTG and <70% on PI, were suppressed at 48/96 weeks (Fig 1A).

• The increase in zBMI was highest among those who started DTG ART-experienced with unsuppressed VL (Fig 1C); this group also had the highest zBMI and weight at start of DTG/PI (Table 2).

• Overall viral suppression was higher on DTG- than PI-based regimens but the differences in the propensity score-matched analysis were not statistically significant.

• Greater gains in zBMI on DTG versus PI were only observed among children ART-experienced and viremic at DTG/PI start. However, numbers were small making it important to corroborate this finding in other datasets.

Table 2: Mean (sd) zBMI and weight at start of DTG/PI by treatment and VL status

<table>
<thead>
<tr>
<th>Treatment/Viral load status</th>
<th>DTG</th>
<th>PI</th>
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<tr>
<td>zBMI</td>
<td>0.90 (1.33)</td>
<td>0.50 (1.33)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>4.5 (2.2)</td>
<td>2.6 (2.4)</td>
</tr>
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</table>

By viral load status at drug start.

• After PS matching, VS was higher on DTG than PI at 48 and 96 weeks though CIs crossed 0 (Fig 2A).

• For children ART-experienced/unsuppressed, zBMI change was higher on average on DTG than PI though the sample size was small (n=24 had zBMI available at 96 weeks) (Fig 2B); in this group weight gain was on average 2kg higher on DTG than PI (Fig 2C).

• For children ART-experienced/unsuppressed, changes in zBMI and weight on DTG and PI were not significantly different (Fig 2B/C).

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Summary

• Overall viral suppression was higher on DTG- than PI-based regimens but the differences in the propensity score-matched analysis were not statistically significant.

• Greater gains in zBMI on DTG versus PI were only observed among children ART-experienced and viremic at DTG/PI start. However, numbers were small making it important to corroborate this finding in other datasets.

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