A Real-World Observational Study on Patients With HIV Who Switched From Nevirapine + 2 Nucleoside Reverse Transcriptase Inhibitors to Dolutegravir/Lamivudine in British Columbia, Canada

Joseph J. de Wet,1,2 Joanna K. Ban,3 Gustavo Verdier,4 Juejing Ling,5 Maria Eberg,5 Andrew Bunko,6 Michael McKimm6

1Spectrum Health, Vancouver, British Columbia, Canada; 2Department of Family Practice, University of British Columbia, Vancouver, British Columbia, Canada; 3GSK, Mississauga, Ontario, Canada; 4Vifor Healthco, Montreal, Quebec, Canada; 5RIVIA, Kirkland, Quebec, Canada

Key Takeaways

- We assessed real-world use of dolutegravir/lamivudine (DTG/3TC) in antiretroviral therapy (ART)-experience, virologically suppressed Canadian PLHIV with HIV who switched from nevirapine extended release (NVP X/R) + 2 nucleoside reverse transcriptase inhibitors (NRTIs) to DTG/3TC due to market discontinuation.

- Results showed that switching to DTG/3TC was effective and well tolerated with low discontinuation and few discontinuations over 12 months in a group of PLHIV who had no reason to switch other than a manufacturing discontinuation.

Introduction

- Despite the availability of single-tablet ART regimens in recent years, some PLHIV remained on multi-tablet NVP X/R + 2 NRTIs due to its excellent safety profile.
- Discontinuation of NVP X/R from the Canadian market on August 20, 2019, required switching to another ART regimen.
- Fixed-dose combination DTG/3TC as a once-daily, single-tablet, 2-drug regimen is recommended as first-line therapy for ART-naïve PLHIV and as a switch option for virologically suppressed PLHIV in US and international guidelines.
- We conducted this analysis to better understand real-world use of DTG/3TC in ART-experienced, virologically suppressed Canadian PLHIV who had previously been using NVP X/R + 2 NRTIs.

Methods

- Study Design: A retrospective, observational cohort study using de-identified electronic medical records from Spectrum Health in British Columbia, Canada (Figure 1).
- PLHIV were selected for inclusion based on the following criteria:
  - ≥18 years of age as of August 20, 2019
  - Virologically suppressed (HIV-1 RNA < 50 c/mL)
  - Switched from NVP X/R to 2 NRTIs to DTG/3TC between August 20, 2019, and April 30, 2020.

Results

Baseline Characteristics

- 69 PLHIV who met study criteria were identified (Table 1).
- Overall, mean age was 54.2 years and 100% of the cohort were male.
- Despite the availability of single-tablet ART regimens in recent years, some PLHIV remained on multi-tablet NVP X/R + 2 NRTIs while 6 continued DTG/3TC.
- The complete case subgroup was composed of all PLHIV with data at baseline and Month 12.

Table 1. Demographics and Baseline Characteristics: Completed Analysis Set

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N=69</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>54.2 (8.6)</td>
<td></td>
</tr>
<tr>
<td>Sex, male, n (%)</td>
<td>69 (100)</td>
<td></td>
</tr>
<tr>
<td>Weight, kg</td>
<td>82.6 (28.3)</td>
<td></td>
</tr>
<tr>
<td>Height, cm</td>
<td>170.0 (7.2)</td>
<td></td>
</tr>
</tbody>
</table>

Clinical Measures

- Median (IQR) duration of follow-up was 17.0 (16.0–17.7) months.
- All endpoints were summarized using descriptive statistics.
- The complete analysis set was composed of PLHIV with follow-up data in the 12-month window (6 months before index date and 6 months after index date).
- The complete case subgroup was composed of all PLHIV with data at baseline and Month 12.

Primary Outcomes

- 69 PLHIV completed the study; 63 remained on DTG/3TC while 6 discontinued DTG/3TC during the study period.
- Among the 6 PLHIV who discontinued DTG/3TC, 5 had HIV-1 RNA <50 c/mL while 1 had HIV-1 RNA >200 c/mL at discontinuation.
- Among PLHIV with available data, mean CD4 cell count increased between baseline and Month 12 (Figure 3).

Secondary Outcomes

- All PLHIV with data at baseline and Month 12, median change from baseline in weight was small (Table 2).
- There were no substantial differences in use of prescriptions for management of weight, diabetes, blood pressure, or lipid levels between Month 12 compared with baseline.

Conclusions

- Results indicate that 12 months after switching from NVP X/R + 2 NRTIs to DTG/3TC, most PLHIV maintained virologic suppression and improved HDL, cell count with few treatment discontinuations, and there was no virologic failure or development of resistance.
- All PLHIV who remained on DTG/3TC until study end maintained HIV-1 RNA <200 c/mL.
- The use of NVP is associated with increases in HDL cholesterol, likely to the increased prevalence of low HDL cholesterol 12 months after switch.
- Findings support the real-world effectiveness and low metabolic impact of DTG/3TC from a switching 3-drug regimen in a group of PLHIV who had no reason to switch other than a manufacturing discontinuation.
- Results are also consistent with results from the phase 3 TANGO and SAILAX studies and real-world studies on DTG/3TC use.

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