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Real-world Experience With the Two-Drug Regimen Dolutegravir/Lamivudine for the Treatment of HIV-1 Among Vulnerable People Living With HIV in Canada: Preliminary Results From a Chart Review Study

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Key Takeaways

- **This study evaluates the real-world use and clinical outcomes among vulnerable people living with HIV (drug use, opioid agonist use, history of homelessness, receiving social assistance, Indigenous identity, or ≥65 years of age with diminished autonomy) who switched to dolutegravir/lamivudine (DTG/3TC)**
- **At 6 months of follow-up, of the vulnerable people living with HIV with viral load results available, 100% remained virally suppressed (<50 copies/mL), while at 12 months of follow-up, 91.7% were virally suppressed (<50 copies/mL) and 100% suppressed at <200 copies/mL**
- **These preliminary results show promising real-world effectiveness outcomes for vulnerable people living with HIV (particularly those who use/inject drugs) who switch to the two-drug combination of DTG/3TC**

Introduction

- Compared to the general population of people living with HIV, vulnerable populations, such as those who use drugs, are disproportionately affected by HIV
- Vulnerable people living with HIV are predisposed to lower adherence to antiretroviral therapy (ART), which may result in poorer virologic suppression, worse health outcomes, and higher HIV transmission rates[1]
- Some may benefit from simpler, once-daily, single-tablet regimens that are effective, well-tolerated, have fewer side effects and drug interactions, and may limit exposure to unnecessary medications
- Dolutegravir/lamivudine (DTG/3TC) is a single-tablet, once-daily, two-drug antiretroviral regimen indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) in both people who are treatment-naive and treatment-experienced[2]
- DTG/3TC was approved by Health Canada in 2019
- There is a need to understand the real-world treatment use and outcomes among vulnerable people living with HIV who switch to DTG/3TC from other ART regimens for the treatment of HIV-1 in Canada

Methods

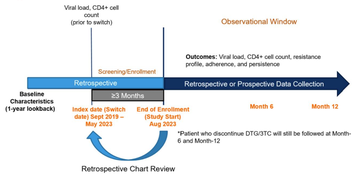
- This is an ongoing retrospective and prospective multi-center cohort study across 11 sites in Canada using chart review methodology
- For study eligibility, people living with HIV (≥18 years) meeting vulnerability criteria must have switched to DTG/3TC (ie, study index date) between September 9, 2019 (ie, the date of Health Canada marketing authorization for DTG/3TC), and May 31, 2023. People were screened for study eligibility after a minimum of 3 months of being on DTG/3TC
- Retrospective data collection was conducted for baseline characteristics, as well as for follow-up data available at study initiation for each site. Prospective data collection was conducted for those without a full 12 months of follow-up data available at site initiation

Vulnerability criteria were determined by having ≥1 of the following:

- Use of injected, inhaled, or ingested drugs at least once over the past year
- On opioid agonist therapy
- Currently, or documented history of, experiencing homelessness or unstable housing
- Currently, or documented history of, receiving social assistance
- Indigenous ancestry (First Nations, Métis, Inuk)
- ≥65 years of age with diminished autonomy or other characteristics that could impact adherence, as assessed by physician

- For this preliminary analysis, descriptive summary statistics were generated for baseline characteristics (≤12 months pre-switch), viral load, and CD4+ cell counts at 6 (±2) and 12 (±2) months post-switch

Figure 1. Study Schematic



Results

Demographic Characteristics

- For this analysis, to date, 20 eligible people living with HIV were included across five Canadian sites (ongoing study)
- Mean age: 49.9 ± 13.0 years; male: 80%; drug use: 80%; opioid agonist therapy: 10%; unstable housing/homelessness: 10%; social assistance: 15%; Indigenous ancestry: 5%; vulnerable senior: 20% (Table 1)

Clinical Characteristics

- Median HIV infection duration was 13.0 years (IQR: 6.7 years)
- The mean recent CD4+ cell count prior to switching to DTG/3TC was 804.5 cells/mm^3 (SD: 266.6 cells/mm^3) (Table 2)
- The mean recent viral load prior to switching to DTG/3TC was 26.6 copies/mL (SD: 10.6 copies/mL) (Table 2)
- The most common reason for switching to DTG/3TC was simplification of ART (n=11/20, 55%) with 9/11 being simplification from dolutegravir/abacavir/lamivudine
- No M184V/I or INSTI resistance was documented in any participant

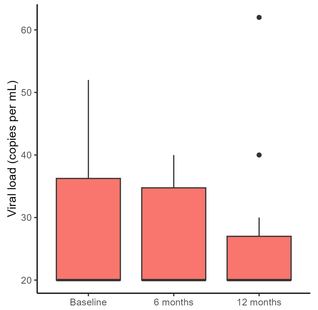
Treatment Patterns

- At the time of analysis, 80% (n=16) had at least 6 months of follow-up
- One individual discontinued DTG/3TC due to intolerance

Clinical Outcomes Following Switch to DTG/3TC

- Rates of viral load and CD4+ cell count monitoring varied in this study
- At 6 months, of those with test results (n=8), 100% were virally suppressed (<50 copies/mL) (Figure 2)
  - Mean viral load was 27 copies/mL (SD: 9 copies/mL), while median viral load was 20 copies/mL (IQR: 15 copies/mL)
- Of those with test results at 6 months (n=8), mean CD4+ cell count was 843 cells/mm^3 (SD: 121 cells/mm^3), while median CD4+ cell count was 815 cells/mm^3 (IQR: 123 cells/mm^3) (Figure 3)
- At 12 months, of those with test results (n=12), 11/12 (91.7%) were virally suppressed (<50 copies/mL) and 12/12 (100%) had viral load of <200 copies/mL (Figure 2)
  - Mean viral load was 27 copies/mL (SD: 13 copies/mL), while median viral load was 20 copies/mL (IQR: 7 copies/mL)
- Of those with test results at 12 months (n=10), mean CD4+ cell count was 891 cells/mm^3 (SD: 217 cells/mm^3), while median CD4+ cell count was 920 cells/mm^3 (IQR: 180 cells/mm^3) (Figure 3)

Figure 2. Most Recent Viral Load at Baseline, 6 Months, and 12 Months



Baseline: median viral load of 20 copies/mL (IQR: 16 copies/mL)

6 months: median viral load of 20 copies/mL (IQR: 15 copies/mL)

12 months: median viral load of 20 copies/mL (IQR: 7 copies/mL)

Table 1. Baseline Demographic Characteristics of Vulnerable People Living With HIV

Demographic characteristics	N=20
Age (years), mean (SD)	49.9 (13)
<65 years, n (%)	15 (75.0)
≥65 years, n (%)*	5 (25.0)
Sex assigned at birth, n (%)	
Male	16 (80.0)
Female	4 (20.0)
Race/ethnicity, n (%)	
White/Caucasian	16 (80.0)
Indigenous/First Nations/Aboriginal	1 (5.0)
Unknown	3 (15.0)
Province/territory, n (%)	
Quebec	17 (85.0)
British Columbia	3 (15.0)
Social assistance, n (%)	
Yes, no other income sources	3 (15.0)
None	11 (55.0)
Unknown	6 (30.0)
Unstable housing or homelessness, n (%)	
Currently experiencing	2 (10.0)
No	6 (30.0)
Unknown	12 (60.0)
Opioid agonist use, n (%)	
Yes	2 (10.0)
No	18 (90.0)
Drug/substance use, n (%)	
Yes	16 (80.0)
Cocaine	5 (25.0)
Crystal methamphetamine	8 (40.0)
Opioids	2 (10.0)
Fentanyl	1 (5.0)
Ecstasy	1 (5.0)
No	3 (15.0)
Unknown	1 (5.0)
Documented history of alcohol use, n (%)	
Yes	12 (60.0)
No	6 (30.0)
Unknown	2 (10.0)
Documented history of cigarette use, n (%)	
Yes	15 (75.0)
No	5 (25.0)

*4 of the 20 people were ≥65 years of age with diminished autonomy or other characteristics that could impact adherence, as assessed by physician (vulnerable senior)

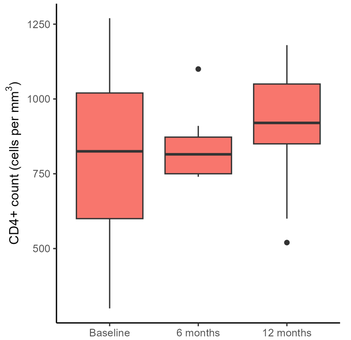
n, number; SD, standard deviation.

Table 2. Baseline Clinical Characteristics of Vulnerable People Living With HIV

Clinical characteristics	N=20
Most recent CD4+ cell count (cells/mm^3), mean (SD)	804.5 (266.6)
Most recent viral load (copies/mL), mean (SD)	26.6 (10.6)
Length of viral suppression (<50 copies/mL) prior to switch, n (%)	
<6 months	1 (5.0)
≥6 months	18 (90.0)
Unknown	1 (5.0)
Prior ART regimens (two most recent), n (%)	
Dolutegravir/abacavir/lamivudine	13 (65.0)
Dolutegravir/emtricitabine/tenofovir disoproxil fumarate	3 (15.0)
Reason for switch to DTG/3TC,* n (%)	
Side effect from previous regimen	4 (20.0)
Simplification of ART	11 (55.0)
*multiple reasons apply	
Hepatitis C diagnoses/treatment, n (%)	3 (15.0)
Liver function (alanine transaminase, U/L), mean (SD)	23.6 (9.5)
Mental illness diagnosis, n (%)	8 (40.0)
Neurological disorder, n (%)	3 (15.0)

ART, antiretroviral therapy; DTG/3TC, dolutegravir/lamivudine; n, number; SD, standard deviation.

Figure 3. Most Recent CD4+ Cell Count at Baseline, 6 Months, and 12 Months



Baseline: median CD4+ cell count of 825 cells/mm^3 (IQR: 420 cells/mm^3)

6 months: median CD4+ cell count of 815 cells/mm^3 (IQR: 123 cells/mm^3)

12 months: median CD4+ cell count of 920 cells/mm^3 (IQR: 180 cells/mm^3)

Conclusions

- Preliminary results of this real-world study show that the two-drug combination of DTG/3TC is effective in vulnerable adults (particularly people who use/inject drugs) living with HIV
- At 6 months of follow-up, of the vulnerable people living with HIV with viral load results, 100% remained virally suppressed (<50 copies/mL), while at 12 months of follow-up, viral suppression was maintained in 91.7% (<50 copies/mL) and 100% (<200 copies/mL) of individuals
- The two-drug combination of DTG/3TC represents an important therapeutic option for vulnerable individuals living with HIV

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